UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, THE STATE OF CALIFORNIA, THE STATE OF COLORADO, THE STATE OF CONNECTICUT, THE STATE OF DELAWARE, THE STATE OF FLORIDA, THE STATE OF GEORGIA, THE STATE OF HAWAII, THE STATE OF ILLINOIS, THE STATE OF INDIANA, THE STATE OF IOWA, THE STATE OF LOUSIANA, THE COMMONWEALTH OF MASSACHUSETTS, THE STATE OF MICHIGAN, THE STATE OF MINNESOTA, THE STATE OF MONTANA, THE STATE OF NEVADA, THE STATE OF NEW JERSEY, THE STATE OF NEW MEXICO, THE STATE OF NEW YORK, THE STATE OF NORTH CAROLINA, THE STATE OF OKLAHOMA, THE STATE OF RHODE ISLAND, THE STATE OF TENNESSEE, THE STATE OF TEXAS, THE COMMONWEALTH OF VIRGINIA, THE STATE OF WASHINGTON, THE STATE OF WISCONSIN AND THE DISTRICT OF COLUMBIA, *ex rel.* JOHN R. BORZILLERI, M.D. Plaintiffs, ABBVIE, INC., AMGEN, INC., BRISTOL-MYERS SQUIBB COMPANY, ELI LILLY AND COMPANY, NOVARTIS PHARMACEUTICALS CORPORATION, PFIZER, INC., SANOFI-AVENTIS U.S. LLC, AETNA, INC., CIGNA CORPORATION, CVS HEALTH CORPORATION, EXPRESS SCRIPTS HOLDING COMPANY, HUMANA, INC. AND UNITEDHEALTH GROUP, INC. Defendants.	CIVIL ACTION NO. 15-Civ. 7881 (JMF) RELATOR'S SECOND AMENDED COMPLAINT PURSUANT TO THE FEDERAL FALSE CLAIMS ACT [31 U.S.C.§3729 *et seq.];* AND SUPPLEMENTAL STATE FALSE CLAIMS ACTS **JURY TRIAL DEMANDED**

NATURE OF THE ACTION

1. John R. Borzilleri, M.D. ("Relator"), a physician and professional healthcare investment fund manager, brings this Qui Tam action on behalf of the United States, the State of California, the State of Colorado, the State of Connecticut, the State of Delaware, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Iowa, the State of Louisiana, the Commonwealth of Massachusetts, the State of Michigan, the State of Minnesota, the State of Montana, the State of Nevada, the State of New Jersey, the State of New Mexico, the State of New York, the State of North Carolina, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the Commonwealth of Virginia, the State of Wisconsin, the State of Washington and the District of Columbia (the "Plaintiff States" and collectively with the United States, the "Government Plaintiffs"), for violations of the Federal False Claims Act, 31 U.S.C. §3729-33 ("FCA") et seq., as well as for violations of the following State False Claims Acts: the California False Claims Act, Cal Government Code §§12650 et seq.; the Colorado Medicaid False Claims Act, Colo. Rev. Stat. §§ 25.5-4-303.5 through 25.5-4-310; the Connecticut False Claims Act, Conn. Gen. Stat. §17b-301b; the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, §§1201 et seq.; the Florida False Claims Act, Fla. Stat. §§ 68.081 et seq.; the Georgia False Medicaid Claims Act, Ga. Code Ann. §§49-4-168 et seq.; Hawaii False Claims Act, Haw. Rev. Stat. §§661-21 et seq.; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. Ann. §§175/1 et seq.; the Indiana Whistleblower Reward and Protection Act, Indiana Code §5-11-5.5; the Iowa False Claims Act, Iowa Code §§ 685.1 through 685.7; the Louisiana Medical Assistance Programs Integrity Law, La. R.S. 46:437.1 et seq.; the Massachusetts False Claims Act, Mass. Ann. Laws. Ch. 12, §§5A et seq.; the Michigan Medicaid False Claims Act, MCLS §§400.601 et seq.; the Minnesota False

Claims Act, Minn. Stat. §§ 15C.01 through 15C.16; the Montana False Claims Act, Mont. Code Anno. §§17-8-401 et seq.; the Nevada False Claims Act, Nev. Rev. Stat. §§357.010 et seq.; the New Jersey False Claims Act, N.J. Stat. §2A:32C-1 et seq.; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§27-14-1 et seq.; the New York False Claims Act, NY CLS St. Fin. §§187 et seq.; the North Carolina False Claims Act, 2009-554 N.C. Sess. Laws §§1-606 et seq.; the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § §5053 et seq.; the Rhode Island False Claims Act, R.I. Gen. Laws §§9-1.1-1 et seq.; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§71-5-171 et seq.; the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code §§36.001 et seq.; the Virginia Fraud Against Taxpayers Act, Va. Code §§8.01-216.1 et seq.; the Washington Medicaid Fraud False Claims Act, Wash. Sess. Laws, Laws of 2012, Ch. 241 §§ 201 through 214; the Wisconsin False Claims for Medical Assistance Act, Wis. Stats. §§20.931; and the District of Columbia False Claims Act, D.C. Code Ann. §§2-308.03 et seq. (hereafter referred to as the "State False Claims Acts") to recover all damages, civil penalties and all other recoveries provided for under the Federal False Claims Act and the State False Claims Acts against the following Defendants, and their affiliates, subsidiaries, agents, successors and assigns: AbbVie, Inc., Amgen, Inc., Bristol-Myers Squibb Company, Eli Lilly and Company, Novartis Pharmaceuticals Corporation, Pfizer, Inc., and sanofi-aventis U.S. LLC (referred to collectively as the "Manufacturer Defendants"); as well as, Aetna, Inc., Cigna Corporation, CVS Health Corporation, Express Scripts Holding Co, Humana, Inc., and UnitedHealth Group, Inc. (referred to collectively as the "Pharmacy Benefit Manager (PBM) Defendants").

INTRODUCTION

2. The United States now faces a national crisis regarding the cost of pharmaceuticals. The cost of treating the most severe and life-threatening medical conditions in the US, such as

cancer, multiple sclerosis, rheumatoid arthritis and many others, with brand name drugs is now typically 4-6 fold higher than it was twelve years ago. The cost increases coincide with the enactment of Medicare Part D in 2003 and its start in 2006.

3. Pharmaceutical spending has been the fastest growing segment of US healthcare sector, which now consumes about 17% of the US economy, double the share of most other developed economies.

4. The skyrocketing US drug costs are placing a severe burden across our society. On a personal level, with therapies, particularly of the "specialty" variety, routinely now costing $70,000-$200,000 or more a year per person, many patients and their families face heartbreaking choices or financial ruin, as they struggle to pay for life-saving drugs. Physicians and other dedicated health professionals strive to help their sickest and most vulnerable patients access life-saving therapies, as beneficiary out-of-pocket "cost-sharing" exposure rises along with the escalating drug prices.

5. The rising drug costs are placing a severe financial burden on American private industry and taxpayers. US businesses are forced to decrease benefits and/or increase premiums/cost-sharing for their employees to remain competitive with foreign competitors who have access to the same drugs at a fraction of the US cost.

6. Furthermore, US taxpayers are funding an ever-increasing portion of these escalating drug costs through government drug programs, especially Medicare Part D.

7. The majority of the vast increase in US drug costs over the past decade has not occurred due to a wave of innovative new drugs reaching the US market. Rather, the primary driver has been the "inexplicable" massive price increases for numerous "old" blockbuster drugs, many of which have faced plummeting clinical use and market share due to severe competition.

8. The vast price increases for these declining drugs could not occur in a properly operating competitive market. The fraudulent price inflation for these "old" blockbuster drugs set the stage for massive US launch prices for new drugs, especially of the "specialty" variety.

9. The pricing abuse among "old" blockbuster and new drugs has been particularly severe in the largest-spending US drug categories, including multiple sclerosis (MS), rheumatoid arthritis, cancer and diabetes. The latter three therapeutic categories are the focus of this Qui Tam action.

10. The Manufacturer and PBM Defendants continue to promulgate the "complexity" surrounding extreme US brand drug pricing.

11. The real cause of widespread sharp increases in the US prices of pharmaceutical drugs is a straightforward price collusion scheme between certain pharmaceutical companies (who set US drug prices) and the uniquely-American, dominant US Pharmacy Benefit Managers (PBMs, who administer access to prescription drugs for the vast majority of Americans).

12. The "Rosetta Stone" behind the brand drug pricing crisis is a secret and seismic shift in the financial compensation model between drug manufacturers and the leading PBMs, which has its origins in the Medicare Part D program.

13. Simply put, the PBM Defendants now make most of their compensation via "service fees" from drug manufacturers, not "rebates", as is still widely-presumed. Legitimate "service fees" are called Bona Fide Service Fees (BFSFs) in Medicare Part D and other government drug programs.

14. As with the Defendants' drugs, the "service fees" are often linked to massive drug prices and price increases, with no relation to legitimate "services" provided by the PBM Defendants and their specialty pharmacy subsidiaries.

15. The four largest PBM Defendants (Express Scripts, CVS Health, UnitedHealth Group and Humana) control drug access for more than 80% of Americans, including the Medicare Part D program where this scheme originated.

16. Two of the dominant PBMs, CVS Health and UnitedHealth Group, have secretive partnerships with two of the smaller US PBM operators, Defendants Aetna and Cigna, respectively. Both parties in these secretive arrangements are benefitting significantly from the "service fee" price collusion scheme outlined in this Complaint.

17. The PBM industry is a uniquely-American business, with a minimal presence outside this country. When Medicare Part D began, the US prices for the Defendant drugs were at parity with the costs in major European countries. Now twelve years later, US prices for these "old", competitively-challenged Defendant brand drugs are routinely 4-8 fold higher domestically, due to massive unilateral US price increases.

18. European drug markets appear to be operating properly, while the US has been greatly distorted by this systemic, collusive "service fee" scheme.

19. In recent years, as the public outcry regarding US drug pricing has escalated, both the pharmaceutical and PBM industries have been increasingly "blaming" each other for egregiously profiting from high US drug prices. The deceitful rhetoric has included all sorts of unverifiable claims regarding rebates, discounts, gross/net drug prices, drug coupons, patient assistance programs, etc.

20. Noticeably absent from the discussion are any significant mention of "manufacturer service fees" or the Medicare Part D program, the true epicenter of massive US brand drug price inflation.

21. In fact, the one topic both the pharmaceutical and PBM industries agree on is that

Medicare Part D has been an astounding success and that its "private competition" model should be a template for all government drug programs. For instance, some corporate interests are pushing for Centers for Medicare and Medicaid (CMS) to expand the Part D "model" into the Part B program. We find this ironic because CMS' own public data clearly indicates that drug price inflation in the Part D program has been far greater than in the Part B program.

22. This ongoing scheme represents among the most severe corporate violations of the public trust in the history of this nation. Many Americans have lost their lives, have lost access to life-savings drugs and have faced financial ruin due to this intentional wide-ranging fraud. The resulting harm has been particularly severe for the most vulnerable elderly and disabled Americans who depend upon the Medicare Part D program.

23. On a broader scale, the financial harm to the public is staggering. Just for the fourteen (14) Defendant drug products, we estimate fraudulent US drug sales of nearly $114 billion over the past decade (about 30% attributable to Medicare Part D), with the scheme ongoing and escalating.

24. The scheme has placed the financial viability of both the Medicare Part D program and our overall health insurance market at risk of insolvency.

25. We remain staunch supporters of the pharmaceutical industry and the need for innovative new drug therapies. This Qui Tam case has nothing to do with that important issue. The primary offenders of this centralized scheme have been a select group of Defendant senior executives, not the dedicated scientists, researchers and other employees, working at these companies.

SUMMARY OF THE FRAUDULENT "SERVICE FEE" SCHEME

26. John R. Borzilleri, M.D. ("Relator") has ascertained that the Manufacturer

Defendants of brand drugs have and continue to make fraudulent overpayments of illegitimate "Bona Fide Service Fees" (BFSFs) far in excess of legally-required "Fair Market Value" (FMV) to the PBM Defendants, as part of a nationwide collusive price inflation scheme in the Medicare Part D program.

27. In Medicare Part D, PBMs were expected to negotiate in good faith with drug manufacturers to obtain "rebates" and lower drug costs for beneficiaries and taxpayers.

28. Instead, the Manufacturer and PBM Defendants entered into an intentional, secretive and fraudulent price inflation scheme, based upon "service fee" contracts, in gross violation of the False Claims Act (FCA) and the Anti-Kickback Statute (AKS).

29. In sharp contrast to drug rebates, BFSFs are the only major financial item excluded from Part D "negotiated price" calculations, thereby leading to higher drug reimbursement prices and greater revenues/profits for the Defendants.

30. As per Center for Medicare and Medicaid Services (CMS) regulations, "service fees" in excess of FMV should be reported by the Drug Manufacturer to the plan sponsor in Medicare Part D. In turn, the plan sponsor (almost always via its contracted PBM) should report "service fees" in excess of FMV to CMS in its Direct and Indirect Remuneration ("DIR") report as a "discount", leading to lower Part D "negotiated" drug prices. The Defendants are intentionally not doing so in order to advance the "service fee" scheme, to fraudulently increase Part D drug prices and maximize their fraudulent profits.

31. Arm's-length negotiations between the Manufacturer and PBM Defendants would have prevented virtually all of the massive 4-6 fold US price inflation for the 14 Defendant brand drugs over the past decade-plus.

32. In recent years, as US "specialty" drug prices have become more extreme and

numerous, fraudulent abuse of plan sponsor Part D "catastrophic" cost-sharing requirements has become widespread to advance the "service fee" scheme.

33. The Manufacturer Defendants (and other biopharmaceutical companies) are routinely "forgiving" the 15% unlimited "catastrophic" cost-sharing exposure of the PBM Defendants, in their dominant roles as Part D plan sponsors. We will discuss this issue in more detail later in the Complaint.

34. BFSFs are payments from drug manufacturers to PBMs and other service vendors in Part D (and other government drug programs) for a wide array of support "services", such as rebate administration, inventory management, drug shipping/delivery, reimbursement/financial assistance, patient education/clinical programs, drug adherence programs, phone support, data reports, etc.

35. The fraudulent Manufacturer Defendant "service fee" payments to the PBM Defendants are standardly calculated via secretive "percent of revenue" contracts, based upon inflated brand drug "list" prices and massive price increases, primarily using Average Wholesale Price (AWP) or the related Wholesale Acquisition Cost (WAC) from public databases.

36. AWP is also the basis for reimbursement for brand drugs in Medicare Part D. As per the US Department of Health and Human Services (HHS), the "negotiated price that the sponsors and beneficiaries pay pharmacies for the ingredient cost of the drug is usually based upon Average Wholesale Price (AWP) discounted by a specified percentage…." Office of Inspector General (OIG), OEI-03-7-00350, Comparing Pharmacy Reimbursement: Medicare Part D to Medicaid, February 2009.

37. These "service fee" payments from the Manufacturer Defendants are linked contractually to massive drug prices, with no relationship to bona fide "support services" being

provided by the PBM Defendants and their specialty pharmacy subsidiaries.

38. In these "service fee" contracts, both Defendant parties are fraudulently inflating US drug "list" prices (and contractually-linked "service fees"), Part D reimbursement levels and their profits, with the additional drug costs largely passed on to taxpayers and patients in Medicare Part D.

39. Massive increases in "service fee" payments to the PBM Defendants have occurred despite a significant decline in actual "support services" being provided for many "old" Defendant "blockbuster" drugs, commensurate with their sharply declining clinical use and prescription volume.

40. According to the Part D regulations, legitimate BFSFs paid by the Manufacturer Defendants to the PBM Defendants in Medicare Part D should:

a. Be paid only for legitimate "support" services, based upon clinical usage of the drug;
b. Represent "reasonable compensation", based upon the actual cost of providing the "service";
c. Be "commercially reasonable" and not be "distorted" by anticompetitive market factors;
d. Be consistent with the "efficient distribution of drugs", at affordable prices for patients.

41. All of these legal requirements for BFSFs are encompassed in the long-established Federal "Four-Part Test", which all BFSFs must "pass" to be considered "bona fide" or "legitimate" in Medicare Part D and other government drug programs. 71 Fed. Reg. 69624, 69667-9.

42. All the Defendants in this Qui Tam case knew or should have known of the clear legal requirements for "legitimate" BFSFs.

43. The "Four-Part Test" requires that:

a. The "itemized" service is actually performed for the manufacturer;

b. The manufacturer actually needs the "service" and is not performing the service itself;

c. The "service fee" is kept by the PBM (or other service providers, such as specialty pharmacies) and not shared with the payer client (otherwise the payment would simply be another form of drug discount); and,

d. The "service fee" payment is paid at "Fair Market Value" (FMV), commensurate with an "arm's length" transaction between unaffiliated parties.

44. In Part D and other government drug programs, drug manufacturers have the legal responsibility to ensure that BFSFs are legitimate and paid at FMV. However, both Defendant parties have extensive legal liability under both the Anti-Kickback Statute (AKS) and the False Claims Acts (FCA).

45. All of the above four components of the "Four Part Test" are commonly being fraudulently violated in the Part D contractual and financial arrangements between the Manufacturer and PBM Defendants.

46. However, the central focus of this case is the wide-ranging evidence of ongoing violations of the "Fair Market Value" (FMV) requirements regarding BFSFs.

47. The abuse has been most severe for the "old" Defendant drugs in declining clinical use, including Amgen's Enbrel (rheumatoid arthritis/psoriasis, FDA-approved 1997), Novartis' Gleevec (cancer, FDA-approved 2001), Sanofi's Lantus (insulin for diabetes, 2000), Eli Lilly's Humulin (insulin for diabetes, 1982), Pfizer's Viagra (erectile dysfunction, 1998), Pfizer's Celebrex (osteoarthritis/pain, 1998), Pfizer's Premarin (hormone replacement/osteoporosis, 1942),

Pfizer's Pristiq (depression, 2008) and Pfizer's Relpax (migraine, 2002).

48. The other drug products targeted in this action are: AbbVie's Humira (rheumatoid arthritis/psoriasis, FDA-approved 2003), Novartis' Tasigna (cancer, 2007), Bristol-Myers Squibb's Sprycel (cancer, 2006) and Pfizer's Chantix (smoking cessation, 2006).

49. The Relator has also filed a separate Qui Tam action, in the US District Court of Rhode Island (CV-14-03-WES), alleging Part D "service fee" pricing fraud pertaining to the US multiple sclerosis (MS) drug market.

50. Following the government's non-intervention decision, the Relator filed a Second Amended Complaint in Rhode Island. The public health and fiscal harm is distinct for each Defendant drug product in both of these Qui Tam actions.

51. BFSFs were employed in other government drug programs, prior to the enactment of Part D. However, Part D was the catalyst for severe BFSF fraud for several key reasons.

52. First, as the first "private competition" federal drug program, Congress placed no limits on brand drug price increases in the program (in sharp contrast to Medicaid), presuming arm's-length negotiation by the PBM Defendants.

53. Second, assuming "manufacturer rebate" negotiations would remain the key target for "cost-savings" and PBM profits, Medicare requires their deduction from Part D "negotiated" prices and requires full disclosure.

54. Third, assuming BFSFs would be for legitimate "support services", CMS excludes these payments from Part D "negotiated" prices.

55. Compounding the situation, CMS placed few reporting requirements and no financial limits on the amounts of BFSFs in the Medicare Part D program.

56. Part D also insulates most beneficiaries from massive price increases because the

majority of drug costs associated with high prices are covered by taxpayers, via the program's subsidies. Most importantly, the Low-Income Subsidies (LIS) cover almost all routine costs for low income beneficiaries, while the Reinsurance Subsidies cover 80% of all extreme drug costs for all Part D beneficiaries above a modest annual limit (only $5,000 in 2018).

57. Finally, the liberal use of financial assistance programs by drug manufacturers (often with the assistance of PBMs) has limited beneficiary out-of-pocket exposure for much of the past decade and aided in deflecting public scrutiny.

58. Driven by these factors, Part D led to a seismic and secretive shift in the US pharmaceutical market and the financial transactions between drug manufacturers and the dominant PBMs.

59. Prior to Medicare Part D, the PBM Defendants made virtually all their profits from the portion of rebates they "retained" in their negotiations with manufacturers.

60. After the arrival of Part D, the PBM Defendants began secretly making the vast majority of their profits from "service fee" payments from drug manufacturers.

61. Wide-ranging US brand drug patent expirations (leading to lower brand sales and fewer brand drug rebate opportunities), have been a key factor propelling the "service fee" scheme to its current stratospheric heights, now more than 15 years after Part D was enacted as part of the Medicare Modernization Act (MMA) of 2003.

62. With generic prescriptions now accounting for more than 90% of US drug prescription volume (up from about 50% when Part D began), both the Manufacturer and PBM Defendants became increasingly dependent on a narrower group of remaining brand drugs for revenues and profits.

63. Further violating the public trust and the law, the financial scheme has intentionally

been kept secret by the Defendants from virtually all affected and influential constituents, including patients and their families, physicians and other healthcare providers, taxpayers, client corporations, insurance plan clients, unions, pension funds, independent pharmacies, patient support organizations, investors, regulators, Congress and the Securities and Exchange Commission (SEC).

64. In April 2018, following the unsealing of our Qui Tam actions, the Relator filed a Whistleblower Complaint (via TCR) with the SEC regarding all the Defendants in both the Rhode Island and Southern District of New York (SDNY) Qui Tam actions. Separate from our Medicare Part D fraud allegations, failure to provide any significant financial disclosures regarding these "service fee" arrangements and their profit contribution represents a gross violation of the SEC "materiality" requirements.

65. The Part D program has been compromised by the near complete control of all key functional roles by the PBM Defendants. In Part D, the PBM Defendants, and their wholly-owned subsidiaries, provide all three of the key Part D functions (plan sponsor, PBM and specialty pharmacy functions) for the majority of Part D plans and beneficiaries.

66. Because CMS depends upon plan sponsors for Part D program oversight, combined ownership and vertical integration has been a key factor enabling this scheme, due to severe conflicts of interest, limited transparency and lax oversight.

67. Based upon the biopharmaceutical industry's own recent incriminating public data, the Manufacturer Defendants are typically contractually paying the PBM Defendants (and their specialty pharmacy subsidiaries) about 8% of US high-cost brand "specialty" drug sales, based upon the massive "list" prices and 4-6 fold price increases. Pharmaceutical Research and Management Association (PhRMA) report, "Follow the Dollar", November 2017.

68. Defendant "specialty" drugs, such as AbbVie's Humira, Amgen's Enbrel and Novartis' Gleevec, typically target smaller patient populations, but at an extreme annual cost of $70-200,000 or more for each patient.

69. In these contracts, after years of massive inflation, the PBM Defendants are receiving astounding "service fees" in the $5,700 range per year for each US patient treated with Humira or Enbrel and in the $12,000 range per year for each US patient treated with Gleevec.

70. Based upon this same industry report, the Manufacturer Defendants are typically paying the PBM Defendants about 4% of "traditional" US brand drug sales, based upon "list" prices, inclusive of massive 4-6 fold price increases.

71. Defendant blockbuster "traditional" brand drugs include Sanofi's Lantus (diabetes), Eli Lilly's Humulin (diabetes), as well as Pfizer's Lyrica (neurologic pain), Viagra (erectile dysfunction) and Celebrex (osteoarthritis, pain).

72. Brand drugs categorized as "traditional" by industry typically target far larger patient populations, at a more modest cost, typically $4,000-7000/patient/year in mid-2018, after the massive price inflation over the past decade.

73. The Part D financial fraud generated by this scheme is far greater for an individual "specialty" vs. "traditional" drug-treated patient. However, the aggregate and cumulative Part D financial fraud for the Defendant "traditional" drugs is also severe, due to their high-volume use.

74. Among "traditional" Defendant drugs, Sanofi's Lantus, a long-acting insulin for the large diabetic population, has been the top-selling drug in Medicare Part D. Pfizer's Lyrica has been among the top-spending Part D drugs in recent years, due to its wide use for diabetic neuropathy and fibromyalgia.

75. Diabetes is the top-spending brand drug category in both Part D and the private

insurance market. We conservatively estimate that approximately 30% of US diabetes drug spending is in the Medicare Part D program.

76. Regarding "specialty" drugs, the rheumatoid arthritis/psoriasis and cancer categories targeted in this action are among the top-spending drug segments in virtually all Medicare Part D and private insurance plans. AbbVie's Humira and Amgen's Enbrel are top-spending products in virtually all plans. We estimate about 30% of the use on these two "blockbuster" drugs is in Medicare Part D.

77. With the high prevalence of cancer in the elderly, the oral chronic myeloid cancer (CML) therapies, Novartis' Gleevec, Novartis' Tasigna and Bristol-Myers Squibb's Sprycel, are heavily used in Medicare Part D. Gleevec was the second top-selling cancer drug on Medicare Part D prior to its early 2016 US patent expiration. We estimate that approximately 60% of US CML drug spending is in the Medicare Part D program.

78. In these collusive contractual "service fee" arrangements, the vast majority of the financial gains from the price increases accrue to the Manufacturer Defendants, as indicated by their SEC-reported US sales.

79. The PBM Defendants, in turn, receive fraudulent "service fees", as "kickbacks", for favorable Manufacturer Defendant drug inclusion/handling in Part D drug formularies and the avoidance of long-established, effective, PBM cost-saving strategies (aggressive rebate negotiations, brand drug "therapeutic substitution" and "formulary restriction" programs, etc.).

80. PBM brand drug "therapeutic substitution" and "formulary restriction" programs are the long-standing mechanisms for the PBM Defendants to obtain brand drug price concessions from drug manufacturers during negotiations.

81. In these standard negotiating practices, the PBM Defendants demand significant

price concessions for placing a brand drug on its formulary and not implementing/enforcing additional restrictions on access, such as prior authorization requirements, high co-pays, high co-insurance, etc.

82. In a normal operating market, had standard PBM Defendant formulary and cost-savings practices been legitimately implemented, the vast majority of price increases for the Defendant drugs would not have occurred over the past twelve years. For products in declining use, price decreases might have been expected.

83. The PBM Defendant negotiating leverage for cost savings should be particularly strong for the "old" Manufacturer Defendant "blockbusters" in declining clinical use in crowded US brand therapeutic categories, including the rheumatoid arthritis, diabetes and CML cancer segments targeted in this action.

84. Furthermore, cost-savings negotiating tactics should be particularly effective in Part D, where the vast majority of the plans and beneficiaries utilize the PBM Defendants' "national formularies".

85. Under the False Claim Act, "kickbacks" in federal programs are, by law, also false claims for reimbursement. While "kickbacks" are a criminal offense, under the FCA, liability only has to be proved by a preponderance of the evidence. 31 U.S.C. § 3731(d) US ex. rel. Pasqua v. Kan-Di-Ki, LLC, 2:10-cv-00965 C.D. CA. (March 8, 2013).

86. Furthermore, both the Manufacturer and PBM Defendants have caused or directly submitted a myriad of false claims via the array of submissions required for reimbursement in the Medicare Part D program, including Prescription Drug Event (PDE) reports, Direct and Indirect Remuneration ("DIR") reports, Part D annual plan bids, as well as financial data required for Part D subsidy reconciliation. (Direct, Low-Income and Catastrophic subsidies).

87. Virtually all Part D submissions for reimbursement pertaining to the Manufacturer Defendant drugs over the past 12 years-plus have been "tainted" by kickbacks and have been false claims.

88. Both Defendant parties, as well as their subsidiaries and their senior executives (Chief Executive Officer and Chief Financial Officer), must "expressly certify" compliance with the Anti-Kickback Statute (AKS) and the False Claim Act (FCA) to participate in Medicare Part D.

89. The wide-ranging legal liability for the PBM Defendants in Part D contrasts sharply with their historic limited exposure in the private insurance sector. Due to lack of fiduciary responsibilities under the Employment Retirement Income Security Act (ERISA), the PBM Defendants have successfully deflected a wide array of private lawsuits alleging abusive business practices over the past several decades.

90. Prior US Department of Justice PBM Defendant case settlements have already established negligence in the FMV of BFSFs as a basis for false claims and kickbacks. United States Settlement Agreement with Advanced PCS (now part of CVS Health), September 7, 2005. United States Settlement Agreement with Medco Health Solutions, October 23, 2006.

91. The states with Qui Tam statutes have been named as plaintiffs, due to severe harm caused by the scheme. States are required to fund about a third of the cost of their high-consuming "dual-eligible" population in the Medicare Part D program. Prior to Part D, these state beneficiaries received their drug benefits via state Medicaid programs. Due to price inflation protections on brand drugs in Medicaid, states are paying fraudulently higher drug costs (4-6 fold higher) for the Defendant products directly due to the Part D pricing scheme.

92. The cumulative and compounding harm to the public fisc from this decade-plus

systemic, ongoing pricing scheme is staggering. Overall, we estimate cumulative fraudulent US sales of about $114 billion between 2006 and 2017 for the 14 Defendant drug products, with about 30% attributable to the Part D program.

93. Our US sales fraud estimates have nearly doubled since our initial SDNY Qui Tam filing in October 2015 due to ongoing, uniform and extreme Manufacturer Defendant price increases.

94. To enable the systemic pricing scheme, we estimate that the Manufacturer Defendants have paid the PBM Defendants fraudulent "service fees" of approximately $7 billion between 2006 and 2017, with about 30% attributable to the Part D program.

95. Our direct "service fees" fraud estimates have more than tripled since our initial SDNY Qui Tam filing in October 2015, due ongoing severe price increases and the Defendant public disclosure of a higher "service fee" contract rate for "specialty" drugs (8% rather than the 4% rate used in our prior filing)

96. For the individual declining-use Defendant products, we estimate that "service fee" payments from the Manufacturer Defendants to the PBM Defendants have increased approximately 5-fold over the decade for each Defendant drug prescription, driven solely by the massive price increases.

97. Our investigation found no legitimate justification for massive increases in "service fees" paid for drugs products with sharply eroding clinical usage.

98. Our investigation failed to identify any legitimate PBM Defendant "support services" attributable to massive price increases, other than potential abusive patient financial support programs required to advance the scheme.

99. Using the Defendant's own data from the November 2017 PhRMA report, the PBM

Defendants are receiving approximately 8-to-11 fold greater compensation, for high-cost "specialty" drugs, via "service fees" from the Manufacturer Defendants compared to their "retained" portion of "manufacturer rebates".

100. Based on the PhRMA data, for "traditional" pharmaceutical products, the PBM Defendants are typically receiving about twice as much compensation from manufacturers via "services fees" relative to "rebates".

101. According to the PhRMA, these manufacturer "service fees" now account for 90-100% of PBM Defendant profits from "specialty" drugs and about 70% of profits for "traditional" drugs.

102. To this day, the majority of independent pharmaceutical and PBM experts still cite "manufacturer rebates" as the primary source of PBM Defendant profits, despite it being invalid now for more than a decade.

103. The gross violation of the Part D regulations, as well as the FCA and the AKS, is even starker when considering "service fee" payments at the aggregate level and the plummeting prescription volume for key Defendant drugs.

104. For numerous of the declining-use Defendant products, we estimate that the Manufacturer Defendants are commonly paying the dominant PBM Defendants approximately four times as much in aggregate annual "service fees" for supporting half or less as many prescriptions and patients compared to a decade ago. In layman's terms pertaining to "services", think of paying someone four times as much money to paint half of your house.

105. The "service fee" fraud has been particularly severe for "specialty" oral cancer drugs, including the Defendant products for CML; namely Novartis' Gleevec and Tasigna, as well as Bristol-Myer's Squibbs' Sprycel.

106. With negotiated "manufacturer rebates" minimal for oral cancer "specialty" drugs, the PBM Defendants are receiving vast "service fees", tied to vast drug prices and price increases, while providing minimal value for beneficiaries and payer clients.

107. As per Express Scripts' CEO, Tim Wentworth: "Alternatively, in oral oncology, for example, rebates are practically nonexistent. Only 2 out of the 88 products pay rebates, yet prices have gone up 100% over five years. You can't blame rebates for that." Express Scripts Fourth Quarter 2016 Earnings Conference Call, February 15, 2017.

108. As such, the PBM Defendants are receiving massive "service fees" on the Manufacturer Defendant CML drugs and other extreme-priced oral "specialty" cancer drugs, with the virtually full "list" prices and price increases passed on to taxpayers and beneficiaries in Medicare Part D.

109. Using the standard PhRMA "8%" contract rate, after 5-fold inflation to the $150,000 cost/patient range prior to its US patent expiry, the PBM Defendants received about $12,000 per year in "service fees" from Novartis for each Gleevec-treated Part D patient or about $1,000 for each monthly prescription of 30 daily pills.

110. With minimal or no rebates, "service fee" abuse has been severe for a wide array of other US oral cancer "specialty" drugs. Other top-spending, long-marketed and fast-inflating oral cancer drugs include: Celgene's Revlimid (multiple myeloma, the top-selling cancer drug in Medicare Part D, AWP $225,000/year), Bayer's Nexavar (renal cell/liver cancer, AWP $136,000 patient/year) and Roche's Tarceva (lung cancer, AWP $123,000 patient/year.

111. Among "traditional" oral drugs, Pfizer has employed the price inflation/"service fee" model for many declining-use "traditional" "blockbuster" oral drugs, such as Lyrica (neurologic pain), Viagra (erectile dysfunction), Premarin (hormone replacement/osteoporosis)

and Celebrex (osteoarthritis, pain).

112. The majority of the prescriptions for these straightforward oral "traditional" brand drugs are simply filled at a local pharmacy or routinely shipped to patients by mail, similar to any generic drug prescription.

113. At the 4-8% contract rates, the PBM Defendants' absolute profit from an individual Defendant drug is obviously modest relative to the profits generated for the Manufacturer Defendants.

114. When this scheme is applied across numerous massively-inflating "blockbuster" US brand drugs and major therapeutic categories, the overall profits for the PBM Defendants are truly astounding.

115. The staggering profit benefit for the PBM Defendants is reflected in the SEC-reported financial statements of Express Scripts, the largest US PBM and the only major public stand-alone PBM.

116. Despite declining revenues and prescription volume over the past 5 years, Express Scripts' annual profits have nearly tripled. In 2013, Express Script's reported revenues of $104 billion and net income of $1.8 billion. In 2017, Express Scripts reported revenues of $100 billion and net income of $4.5 billion.

117. Escalating manufacturer "service fee" payments, tied to massive brand drug prices and price increases, has been the primary driver of Express Script's remarkable profit growth in recent years, despite severe competition from and market share losses to other leading PBM Defendants.

118. A substantial 30% decrease in Express Scripts' Selling, General and Administrative (S,G&A) spending over the 5 years, from $4.6 billion in 2013 to $3.3 billion in 2017, has been a

major contributor to the company's profit growth.

119. Express Scripts' sharply declining S,G&A spending trends indicate that escalating "support services" have not been provided to drug manufacturers as the "fee" payments have accelerated in recent years.

120. In fact, Express Scripts S,G&A trends indicate that the PBM is getting paid a lot more money by the drug manufacturers, in aggregate, for doing considerably less legitimate "support" work.

121. Besides Express Scripts, all the other PBM Defendants have also reported remarkable profit growth over the past 5 years. However, because of their more diversified business models, and their limited financial disclosures, we are unable to assign profits specifically to their PBM/specialty pharmacy subsidiaries.

122. For all the PBM Defendants, we expect discovery to determine that the manufacturer "service fee" scheme has been a primary driver of both their PBM and overall corporate profit growth over the past decade.

123. The evidence of this systemic "service fee" scheme is overwhelming. This pharmaceutical/PBM collusive "service fee" scheme is the "Rosetta Stone" behind virtually all instances of "inexplicable" massive US brand drug price inflation over the past decade. In fact, this scheme, with its origins in Medicare Part D, is the only viable explanation.

124. The systemic scheme, which began with the large biopharmaceutical and PBM companies, has also been aggressively employed by an array of smaller companies. Notable examples include Mallinckrodt's Acthar Gel, Mylan's Epipen, Turig's Daraprim, as well as the broad product portfolios of Valeant and Horizon Pharmaceuticals.

125. The major pharmaceutical and PBM corporations have done a remarkable job of

keeping media and other investigative efforts focused on these few small "bad actors".

126. Notably, the aggregate US patient and financial harm of just one of the "blockbuster" products in this case, driven by the same scheme, dwarfs that of these combined small companies.

127. For example, even after its 5,000% price increase, the annual US sales of Turig's Daraprim were only approximately $10 million.

128. The Relator's first hand and investigative evidence of the "service fee" scheme is extensive and conclusive. The evidence includes:

a. In October 2013, the Relator attended a conference at which 50-60 directly-involved "corporate insiders" discussed the scheme openly. Representative "insider" quotes from the conference include: a) compensation for service providers from manufacturers had "shifted from rebates to fees"; b)" fees were the key to government pricing"; c) service fee agreements were the "main source of income"; d) service vendors "all want percent of revenue deals"; e) the contracts are not being "refreshed" for price increases; and f) manufacturers need to "consider whether percent of sales can be consistent with FMV as prices rise".

b. In December 2014, a pharmaceutical CEO discussed the details of the scheme with the Relator in a private investor meeting. Key quotes include: a) "well, PBMs don't make their money off rebates anymore, PBMs make their money through service fees"; b) to put through big price increases, you just have to "play ball with them", via service fee contracts.

c. The Relator has verified the scheme in private discussions with an array of highly-experienced independent PBM consultants.

d. Public disclosure of PBM Defendant client contracts, and related public commentary, verify the scheme. Several instructive Express Scripts and CVS Health PBM client contracts are discussed later in this Complaint.

e. Recent public commentary from PBM Defendant senior executives verify the industry's reliance on the "service fees", rather than rebates for profits.

f. For the first time, the pharmaceutical industry itself, via its closely-controlled lobbying organization, the Pharmaceutical Research and Management Association (PhRMA), publicly corroborated the scheme in a November 2017 report. The CEOs of most of the Manufacturer Defendants are current board members of PhRMA.

g. The PBM Defendants also corroborated the "service fee" scheme in the US rheumatoid arthritis market, in a June 2017 report from the PCMA, the PBM industry's closely-controlled lobbying organization.

JURISDICTION AND VENUE

129. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331, 28 U.S.C. §1367, and 31 U.S.C. §3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730. Under 31 U.S.C. 3730(e), there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint. The Relator is the original source of the investigation and allegations in this Complaint.

130. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C.§3732(a) because that section authorizes nationwide service of process and because the Defendants have minimum contacts with the United States. Moreover, the Defendants can be found in this District, have appointed a registered agent for service of process in this District, and

/or transact business in this District.

131. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a) because the Defendants can be found in and/or transact business in this District. At all times relevant to this Complaint, Defendants regularly conducted substantial business within this District, maintained employees in this District, and/or made significant sales within this District. In addition, statutory violations, as alleged herein, occurred in this District.

PARTIES

132. Plaintiff/Relator John R. Borzilleri, M.D. ("Relator"), an investment fund manager and physician, is a resident of Cutchogue, New York. He has been a professional healthcare industry investment analyst for 25+ years. The Relator is a licensed physician in the State of New York, with an MBA degree from Columbia University.

133. Defendant AbbVie, Inc. ("AbbVie") is a Delaware corporation, with its U.S. headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. On January 1, 2013, Bayer became an independent, publicly-traded company as a result of the distribution by Abbott Laboratories of 100 percent of the outstanding common stock of AbbVie to Abbott's shareholders. AbbVie focuses on anti-inflammatory conditions, infectious disease, and hormone replacement. AbbVie reported worldwide revenue $28.2 billion in 2017. Pertaining to this case, AbbVie markets Humira in the United States for the treatment of rheumatoid arthritis, psoriatic arthritis, psoriasis, Crohn's disease, ulcerative colitis and ankylosing spondylitis. In 2017, Humira accounted for 65% of AbbVie's global sales.

134. Defendant Amgen, Inc. ("Amgen") is a Delaware corporation, headquartered at One Amgen Center Drive, Thousand Oaks, California 91320-1799. Amgen discovers, develops, manufactures, and markets human therapeutics in the oncology, inflammatory, cardiovascular and

renal disease categories. Amgen reported worldwide sales of $22.8 billion in 2017. Pertaining to this case, Amgen markets Enbrel in the United States for the treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis and plaque psoriasis. Enbrel accounted for 27% of Amgen's global product sales in 2017.

135. Defendant Bristol-Myers Squibb Company ("Bristol-Myers Squibb") is a Delaware corporation, headquartered at 345 Park Avenue, New York, NY 10154. Bristol-Myers Squibb primarily generates revenues in the oncology, virology, cardiovascular, neuroscience, immunology, fibrosis and genetic diseases therapeutic areas. Bristol-Myers Squibb reported worldwide sales of $20.8 billion in 2017, with 55% of sales in the United States. Pertaining to this case, Bristol-Myers Squibb markets Sprycel in the United States for the treatment of chronic myeloid leukemia. Sprycel accounted for 10% of Bristol-Myers Squibb's US revenues in 2017.

136. Defendant Eli Lilly and Company ("Eli Lilly") is an Indiana corporation, headquartered at Lilly Corporate Center, Indianapolis, Indiana 46285. Eli Lilly is a leading healthcare company focused on human pharmaceuticals and animal health. In its human pharmaceutical division, Eli Lilly focuses on the diabetes, oncology, neuroscience and cardiovascular therapeutic areas. Eli Lilly reported worldwide sales of $22.9 billion in 2017, with 56% of sales in the United States. Pertaining to this case, Eli Lilly markets Humulin in the United States for the treatment of diabetes. Humulin accounted for 6% of Eli Lilly's global revenues in 2017.

137. Defendant Novartis Pharmaceuticals Corporation (“Novartis”) researches, develops, manufactures and distributes medications. Novartis is owned, through a United States holding company, by Novartis International AG, a pharmaceutical manufacturer headquartered in Basel, Switzerland. Novartis’ corporate headquarters in the United States are in East Hanover,

New Jersey. Novartis reported worldwide sales of $49.1 billion in 2017. Related to this Complaint, Novartis markets Gleevec and Tasigna for the treatment of chronic myeloid leukemia (CML).

138. Defendant Pfizer, Inc. ("Pfizer"), a Delaware corporation, is headquartered in New York City at 235 East 42nd Street, New York, New York 10017. Pfizer focuses on therapies for cardiovascular/metabolic disease, immunology, inflammation, oncology and neuroscience. Pfizer reported worldwide revenues of $52.5 billion in 2017. Related to this case, Pfizer markets Lyrica (neurologic pain), Viagra (erectile dysfunction), Celebrex (osteoarthritis/pain), Chantix (smoking cessation), Premarin (hormone replacement/osteoporosis), Pristiq (depression) and Relpax (migraines). The brand drugs targeted in this case accounted for approximately 30% of Pfizer's US pharmaceutical sales in 2017.

139. Defendant sanofi-aventis U.S. LLC ("Sanofi") is a Delaware limited liability corporation with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi-aventis U.S. LLC operates as a subsidiary of Sanofi. Sanofi manufacturers and sells Lantus for the treatment of diabetes. In 2017, Lantus accounted for approximately 19% of revenues.

140. Defendants AbbVie, Inc., Amgen, Inc., Bristol-Myers Squibb Company, Eli Lilly and Company, Novartis Pharmaceutical Corporation, Pfizer, Inc. and sanofi-aventis U.S. LLC are collectively identified as the "Manufacturer Defendants" in this Complaint.

141. Defendant Aetna, Inc. ("Aetna"), headquartered in Hartford, CT, and its subsidiaries, is one of the nation's leading diversified health care benefits companies. Aetna's headquarters are located at 151 Farmington Ave, Hartford, CT 06156. Through annual contracts with CMS, Aetna offers HMO and PPO products for eligible individuals in certain geographic areas through the Medicare Advantage program. Aetna is a national provider of the Medicare Part

D Prescription Drug Program ("PDP") in all 50 states and Washington, D.C. to both individuals and employer groups. Aetna offers pharmacy benefit management services and specialty and mail order pharmacy services to its members. Aetna's pharmacy fulfillment services are delivered by Aetna Specialty Pharmacy ("ASP") and Aetna Rx Home Delivery®. ASP compounds and dispenses specialty medications and offers certain support services associated with specialty medications. In 2017, Aetna reported revenues of $60.5 billion. In 2011, CVS Health began to perform the administration of selected functions for Aetna's retail pharmacy network contracting and claims administration; mail order and specialty pharmacy order fulfillment and inventory purchasing and management; and certain administrative services for Aetna. In December 2017, Defendant CVS Health announced an agreement to acquire Aetna, Inc.

142. Defendant Cigna Corporation ("Cigna"), headquartered in Bloomfield, CT, and its subsidiaries, is a global health services provider of medical, dental, disability, life and accident insurance and related products and services. Cigna's headquarters are located at 900 Cottage Grove Road, Bloomfield, CT 06002. Cigna's Medicare Part D plans are available in all 50 states and the District of Columbia. With a network of over 65,000 contracted pharmacies, Cigna Pharmacy Management is a comprehensive pharmacy benefits manager ("PBM") offering clinical integration programs and specialty pharmacy solutions. Cigna Pharmacy Management offers fast, cost-effective mail order, telephone and on-line pharmaceutical fulfillment services through our home delivery operation. Under a 2013 agreement, Catamaran Corporation (now part of Defendant UnitedHealth Group, Inc.) provides Cigna with access to their technology and service platforms, prescription drug procurement and inventory management capabilities, retail network contracting and claims processing services. Cigna reported revenues and net income of $41.6 billion and $2.23 billion, respectively, in 2017. In March 2018, Cigna announced an agreement to acquire Defendant

Express Scripts.

143. Defendant CVS Health Corporation ("CVS Health"), headquartered in Woonsocket, RI, and its subsidiaries, is the largest integrated pharmacy health care provider in the United States. CVS Health's headquarters are located at One CVS Drive, Woonsocket, RI 02895. CVS Health's Pharmacy Services Segment provides a full range of PBM services to our clients consisting primarily of employers, insurance companies, unions, government employee groups, managed care organizations ("MCOs") and other sponsors of health benefit plans and individuals throughout the United States. In addition, through our SilverScript Insurance Company ("SilverScript") subsidiary, CVS Health is a national provider of drug benefits to eligible beneficiaries under the Federal Government's Medicare Part D program. The Pharmacy Services Segment operates under the CVS Caremark® Pharmacy Services, Caremark®, CVS Caremark®, CarePlus CVS/pharmacy®, RxAmerica®, Accordant®, SilverScript® and Novologix® names. CVS Caremark participates in the administration of the drug benefit added to the Medicare program under Part D of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA, Medicare Part D") through the provision of PBM services to its health plan clients and other clients that have qualified as Medicare Part D prescription drug plans ("PDP"). CVS Health reported revenues and net income of $184.8 billion and $6.6 billion, respectively, in 2017. In December 2017, CVS Health announced an agreement to acquire Defendant Aetna, Inc.

144. Defendant Express Scripts Holding Company ("Express Scripts"), headquartered in St. Louis, MO, and its subsidiaries, is the largest PBM company in the United States, offering a full range of services to our clients, which include managed care organizations, health insurers, third-party administrators, employers, union-sponsored benefit plans, workers' compensation plans and government health programs. Express Scripts headquarters are located at One Express

Way, St. Louis, MO 63121. Through its licensed insurance subsidiaries (i.e., Express Scripts Insurance Company ("ESIC"), Medco Containment Life Insurance Company and Medco Containment Insurance Company of New York), Express Scripts operates as Part D PDP sponsors offering PDP coverage and services to clients and Part D beneficiaries. Express Scripts, through our core PBM business, provide Part D-related products and services to other PDP sponsors, MA-PDPs and other employers and clients offering Part D benefits to Part D eligible beneficiaries. Express Script's specialty pharmacy subsidiary, Accredo Health Group ("Accredo®"), is focused on dispensing infused, injectable, inhaled and oral drugs that require a higher level of clinical services and support compared to what typically is available from traditional pharmacies. Express Scripts reported revenues and net income of $100 billion and $4.5 billion, respectively, in 2017. In March 2018, Defendant Cigna announced an agreement to acquire Defendant Express Scripts.

145. Defendant Humana, Inc. ("Humana"), headquartered in Louisville, KY, and its subsidiaries, is a leading health care company that offers a wide range of insurance products and health and wellness services. Humana's headquarters are located at 500 West Main Street, Louisville, KY 40202. During 2017, 79% of Humana's total premiums and services revenue were derived from contracts with the federal government. Most Humana Medicare Advantage plans offer the prescription drug benefit under Part D as part of the basic plan, subject to cost sharing and other limitations. Humana offers stand-alone prescription drug plans, or PDPs, under Medicare Part D, including a PDP plan co-branded with Wal-Mart Stores, Inc., or the Humana-Walmart plan. Humana, Inc. reported revenues and net income of $52.8 billion and $2.45 billion, respectively, in 2017.

146. Defendant UnitedHealth Group, Inc., ("UnitedHealth") headquartered in Minnetonka, MN, and its subsidiaries, is a diversified health and well-being company.

UnitedHealthcare provides health care benefits to a full spectrum of customers and markets. UnitedHealth Group's headquarters are located at 9900 Bren Road East, Minnetonka, MN 55343. UnitedHealthcare Medicare & Retirement delivers health and well-being benefits for Medicare beneficiaries and retirees. UnitedHealthcare Community & State manages health care benefit programs on behalf of state Medicaid and community programs and their participants. UnitedHealth's Optum division is a health services business serving the broad health care marketplace, including payers, care providers, employers, government, life sciences companies and consumers, through its OptumHealth, OptumInsight and OptumRx businesses. UnitedHealthcare Medicare & Retirement provides Medicare Part D benefits to beneficiaries throughout the United States and its territories through its Medicare Advantage and stand-alone Medicare Part D plans. OptumRx is UnitedHealth's full service Pharmacy Benefit Manager (PBM) subsidiary. UnitedHealthcare Medicare & Retirement offers two standalone Medicare Part D plans: the AARP Medicare Rx Preferred and the AARP Medicare Rx Saver plans. In 2015, UnitedHealth acquired the PBM Catamaran Corporation. UnitedHealth Group, Inc. reported revenues and net income of $201.2 billion and $10.6 billion, respectively, in 2017.

147. Defendants Aetna, Inc., Cigna Corporation, CVS Health Corporation, Express Scripts Holding Company, Humana, Inc. and UnitedHealth Group, Inc., are collectively identified as the "PBM Defendants" in this Complaint.

BACKGROUND INFORMATION

A. The Medicare Program

148. Medicare is a federally funded and administered health insurance program for certain groups, primarily elderly and disabled persons. The Department of Health and Human Services ("HHS") administers the Medicare program through the Centers for Medicare and

Medicaid Services ("CMS"). There are four major components to the Medicare program:

a) Part A, the hospital insurance benefits program.
b) Part B, the supplemental medical insurance benefits program, which generally pays for a percentage of certain medical and other health services, including physician services.
c) Part C, the Medicare Advantage program, which allows CMS to contract with public and private entities to provide, at a minimum, Medicare Part A and B benefits to certain Medicare beneficiaries.
d) Part D, the voluntary prescription drug benefit program.42 U.S.C. § 1395w-101, et seq.

B. The Medicare Part D Program

149. Part D was established in 2003 by the Medicare Prescription Drug, Improvement, and Modernization Act, which set up a voluntary prescription benefits program for Medicare enrollees. Part D became effective January 1, 2006. Unlike Parts A and B, Medicare Part D is based on a private market model, wherein Medicare contracts with private entities, known as Part D "sponsors" to administer prescription drug plans. Part D benefits are provided by a Part D plan sponsor, which is either a prescription drug plan ("PDP"), a Medicare Advantage organization plan ("MA-PD"), or a Program of All-Inclusive Care for the Elderly ("PACE").

150. A Part D sponsor submits a bid in the year prior to the calendar year in which Part D benefits will actually be delivered. The bid contains a per member per month ("PMPM") cost estimate for providing Part D benefits to an average Medicare beneficiary in a particular geographic area. From the bids, CMS calculates nationwide and regional benchmarks which represent the average PMPM cost. If the Part D plan sponsor's bid exceeds the benchmark, the enrolled beneficiary must pay the difference as part of a monthly premium.

151. When a pharmacy dispenses drugs to a Medicare beneficiary, it submits an electronic claim to the beneficiary's Part D plan and receives reimbursement from the plan sponsor for the costs not paid by the beneficiary. The Part D plan sponsor then notifies CMS that a drug

has been purchased and dispensed through a document called a Prescription Drug Event ("PDE") record, which includes the amount paid to the pharmacy.

152. As a condition for receiving its monthly payment from CMS, a Part D Plan sponsor must certify the accuracy, completeness and truthfulness of all data related to the payment, which may include enrollment information, claims data, bid submission data, and any other data specified by CMS. 42 C.F.R. § 423.505(k)(1). If the claims data has been generated by a subcontractor of a Part D plan sponsor, such as a PBM, that entity must "similarly certify" that the claims data it has generated is accurate, complete and truthful, and must acknowledge that it will be used to obtain federal reimbursement. 42 C.F.R. § 452.505(k)(3).

153. Part D Plan sponsors must certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse. 42 C.F.R. § 423.505(h)(1). CMS regulations require that all subcontracts between Part D plan sponsors and downstream entities, including pharmacies and PBMs, contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions. 42 C.F.R. § 423.505(i)(4)(iv).

154. Part D Plan sponsors subcontract with many entities to provide drugs to the Medicare Part D beneficiaries enrolled in their plans, including subcontracts with PBMs and specialty pharmacies. PBMs can provide a variety of services to sponsors to help manage their prescription drug benefit. These services include processing prescription drug claims, contracting with pharmacies, managing formularies, as well as negotiating rebates with drug manufacturers. PBMs can be compensated for these services in a variety of ways, including receiving a fixed payment per claim or retaining a percentage of sponsors' rebates.

155. PBMs can also be directly compensated by drug manufacturers via designated

"bona fide service fees" (BFSFs) for a wide array of product-related "services", such as inventory management, patient education, phone support, shipping, reimbursement assistance, data reports, etc., which would have otherwise been performed by the manufacturer. Legitimate BFSFs, paid at FMV, are excluded from government "negotiated price" calculations.

156. CMS has established a unique bid and reimbursement process in the administration of Part D with plan sponsors. Under Medicare Part D, plan sponsors are required to submit bids to CMS in the first week of June for the following calendar plan year. The bids are based upon the sponsor's estimate of its anticipated monthly drug costs for Part D beneficiaries in the plan, as well as administrative costs and expected profit. OIG Report, Medicare Part D Reconciliation Payments for 2006 and 2007, OEI-02-08-00460, September 2009. CMS uses the submitted data to determine individual plan premium rates and monthly subsidy payments made to plan sponsors for the following calendar plan year. The monthly subsidy payment schedule of Part D is designed to help plans effectively manage "cash flow" during a plan year as actual drug costs accrue.

157. The plan sponsor bid cost estimates and related monthly subsidy payments consist of four distinct tranches. First, the sponsor must provide a cost estimate for the "basic" Part D benefit for a beneficiary of "average" health in the plan, for which it receives monthly "Regular Subsidy" payments. According to CMS, the "Regular Subsidy" monthly payments for Part D plans across the US are relatively similar since the amounts are based upon national beneficiary cost averages, with modest adjustments for age and health status in each particular plan.

158. Second, the plan sponsor must provide an estimate of the benefit cost for low-income (LIS) beneficiaries (approximately 30% of overall Part D enrollment) in the plan for the following calendar year, for which CMS provides monthly "Low-Income (LIS) Subsidy" payments. LIS beneficiaries are low-income elderly and disabled people, who commonly are

afflicted with severe chronic medical conditions that often necessitate treatment with high-priced specialty drugs. Other than small copayments, CMS covers virtually all cost-sharing requirements for LIS beneficiaries in Medicare Part D.

159. Third, the sponsor must estimate the cost of providing "catastrophic" drug coverage for Part D beneficiaries whose annual out-of-pocket spending exceeds the annual maximum threshold ($3,600 in 2006, rising to $5,000 in 2018). For "catastrophic" drug costs, CMS covers 80% of the estimated costs via monthly "Reinsurance Subsidy" payments; with plan sponsors and non-LIS beneficiaries responsible for 15% and 5% of spending over the threshold, respectively. In Part D, the use of high-priced specialty drugs is the primary driver of crossing the annual "catastrophic" spending threshold. In contrast to "Regular Subsidy" payments, monthly "LIS Subsidy" and "Reinsurance Subsidy" payments among plans can vary widely, depending upon the enrollment and health status characteristics of a particular plan.

160. Starting in 2011, CMS added the "Gap Discount Subsidy" as part of the ACA legislation, which requires drug manufacturers to provide price discounts to all Part D beneficiaries in the so-called "donut hole" coverage window. In plan bid submissions, plan sponsors must estimate the amount of manufacturer "donut hole" discounts for the following calendar year, for which CMS provides monthly "Gap Discount Subsidy" payments. Since CMS hired a Third Party Administrator (TPA), Palmetto GBA, to administer the Gap Discount program, the "Gap Discount Subsidy" payments appear to be "pass through" amounts from manufacturers to plans sponsors.

161. Part D plan sponsors must provide detailed information to CMS in order to track performance, reconcile subsidy payments and to aid in the detection/prevention of fraud. In administering Part D, plan sponsors are required to submit a "Prescription Drug Event" ("PDE") record for each prescription for all covered drugs dispensed to enrollees. The PDE includes more

than 50 different fields of data, including end-user pharmacy drug cost data. Notably, the PDE does not provide drug costs paid by PBMs to drug manufacturers.

162. In addition, sponsors must submit quarterly and year-end DIR ("Direct and Indirect Remuneration") reports to CMS to disclose any rebates or price concessions, which almost entirely come from manufacturers via PBM negotiations for the vast majority of plans.

163. Both the PDE and DIR data are "self-reported", with apparently limited CMS oversight or verification. Medicare Part D - Prescription Drug Event Reconciliation Process, A-18-08-30102, June 1, 2010. For the vast majority of Part D plans, the PDE and DIR reports are prepared by contracted PBMs, with limited controls by either CMS or unaffiliated plan sponsors.

164. Both “Low-Income Subsidy” and “Reinsurance Subsidy” plan sponsor payments undergo a reconciliation process after each plan year. In the case of "Low-Income Subsidy" payments, CMS guarantees full reimbursement of any unforeseen LIS cost-sharing requirements. In reconciliation, the cost-sharing responsibilities for excess "catastrophic" drug spending are the same as during the bid process. Namely, CMS covers 80% of unlimited excess costs, with the plan sponsor and beneficiary responsible for 15% and 5% (for non-LIS beneficiaries only), respectively.

165. As part of the 2003 MMA legislation, the drug benefit for many of the highest cost, most-severely ill beneficiaries "dual eligibles" beneficiaries were transferred, without recourse, from state Medicaid programs to Medicare Part D. "Dual eligibles" are low-income elderly and disabled beneficiaries eligible for both Medicaid and Medicare benefits. Former State "dual eligibles" account for about two-thirds of Part D LIS beneficiaries which, in turn, have historically accounted for the majority (up to 70% in early program years) of Part D premium-priced “specialty” drug spending.

166. By law, each State is required to fund a significant portion of Medicare Part D spending for their respective "dual eligible" beneficiaries via "phased-down contribution" or "clawback" payments to CMS paid on a monthly basis. In the program years 2006 through 2014, State "clawback" payments accounted for 32-37% of Part D LIS Subsidy costs each year. Furthermore, the State Part D financial responsibilities are legally tied to Federal Medicaid matching transfers. As such, if any State fails or refuses to pay its CMS-determined "clawback" payments, the same amount will be deducted from its scheduled Federal Medicaid matching funds. Overall, States made cumulative "clawback" payments to CMS of $61.8 billion for the years 2006 through 2014.

167. Prior to Medicare Part D, State "dual eligible" beneficiaries received their outpatient drug benefit via State Medicaid programs. Medicaid requires additional manufacturer rebates for brand price increases greater than inflation (CPI-Urban), whereas Medicare Part D provides no such protection.

168. The Part D regulations clearly indicate that plan sponsors, as well as PBM/specialty pharmacy subcontractors, are liable under the False Claims Act for fraudulent data submissions to CMS due to their express requirement to "certify" compliance with regulations as a prerequisite for participation and payment. In addition, the Chief Executive Officer (CEO) and the Chief Financial Officer (CFO must individually expressly "certify" compliance. The provision of C.F.R. § 423.505, entitled "Certification of data that determines payment" states:

a) General rule. *"As a condition of receiving a monthly payment under subpart G of this part (or fallback entities, payment under subpart Q of this part), the Part D plan sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness*

of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies."

b) Certification of claims data. *"The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement. If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based upon best knowledge, information and belief) the accuracy, completeness, and truthfulness of the data ad acknowledge that the claims data will be used for the purposes of Federal reimbursement."*

c) Certification of bid submission data. *"The CEO, CFO, or an individual delegated the authority to sign on behalf of these officers, and who directly reports to the officer, must certify (based on best knowledge, information, and belief) that the information in its bids submission and assumptions related to projected reinsurance and low-income cost sharing subsidies is accurate, complete, and truthful and fully conforms to the requirements in § 423.265."*

d) Certification of allowable costs for risk corridor and reinsurance information. *"The Chief Executive Officer, Chief Financial Officer or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information provided for purposes of supporting allowable costs as defined in § 423.308 of this part, including data submitted to CMS regarding direct and indirect remuneration (DIR) that serves to reduce the costs incurred by the Part D sponsor for Part D drugs, is accurate, complete, and truthful and fully conforms to the requirements in § 423.336 and § 423.343 of this part and acknowledge that this is information will be used for the purposes of obtaining Federal reimbursement."*

DETAILS OF THE FALSE CLAIMS/KICKBACK VIOLATION PATHWAY

169. **For the Manufacturer Defendants:**

1) The Manufacturer Defendants knowingly made fraudulent overpayments of *"Bona Fide Service Fees" ("BFSFs")* far in excess of the legally-required *"Fair Market Value" ("FMV")* to the PBM Defendants, as well as their subsidiaries and partners, in the Medicare Part D program.
2) These fraudulent FMV BFSF payments are straightforward *"kickbacks"* by Manufacturer Defendants to the PBM Defendants to enable the massive price increases, to gain formulary access and to obviate standard PBM cost-savings practices that would lead to far lower Defendant drug prices in highly-competitive US markets.
3) By statute and law, *"kickbacks"* are also direct false claims according to the False Claims Act.
4) According to *31 U.S. code 3729*, anyone who *"knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval"* faces liability. The Manufacturer Defendants have "*caused"* the PBM Defendants to submit a wide array of false claims to federal and state governments for reimbursement, including PDE reports, DIR reports, annual plan sponsor bids, and data required for annual reconciliation of Part D subsidies.
5) As per the regulations, *"service fees"* in excess of FMV should be reported by the drug manufacturer to the plan sponsor. In turn, the plan sponsor (usually via its contracted PBM) should report the excessive *"service fees"* to CMS in its DIR report as a *"discount"*, leading to lower Part D drug prices. The Defendants are intentionally not

doing so in order to advance the *"service fee"* scheme, to fraudulently increase Part D drug prices and maximize their fraudulent profits.

6) The minimal direct Part D reporting requirements regarding BFSFs for the Manufacturer Defendants has been a central factor abetting the fraudulent scheme. As such, we view this fraud as primarily as *"fraud of exclusion"*, especially pertaining to Direct and Indirect Remuneration *("DIR")* reports.
7) As per the law, the Manufacturer Defendant legal liability regarding BFSFs is independent of its Part D reporting requirements, or lack thereof.
8) The *"express certification"* requirements of the Manufacturer Defendants, as well as their participating subsidiaries, against violation of the AKS and the FCA also clearly establishes liability.
9) For each Defendant, the CEO and CFO must also *"expressly certify"* compliance with applicable laws, including the AKS and the FCA.

170. <u>For the PBM Defendants</u>:

1) The fraudulent Manufacturer Defendants FMV BFSF overpayments to the PBM Defendants are "kickbacks" (i.e., "payments for referral") and a violation of the Anti-Kickback Statute ("AKS").
2) The willful receipt of these *"kickbacks"* is a criminal offense by all Defendant parties because the Part D regulations require all participants, including manufacturers, plan sponsors, PBMs, specialty pharmacies, and other First Tier, Downstream and Related Entities (FDRs), to *"expressly certify"* compliance with all relevant laws, including the AKS and FCA.

3) The PBM Defendants, in their role as PBMs, specialty pharmacies and plan sponsors, have directly submitted a wide array of false claims for reimbursement, including PDE reports, DIR reports, annual plan sponsor bids, and data required for annual reconciliation of Part D subsidies.
4) Virtually all Part D submissions impacting reimbursement for the Defendant drugs, for most of the past 12 years, are fraudulent and tainted by the systemic scheme.
5) Due their *"express certification"* requirements and coordination of the scheme, the Defendant CEOs and CFOs of these corporations may also be accountable for the AKS and FCA violations.

DETAILS REGARDING THE STATE FALSE CLAIMS VIOLATIONS

171. In Medicare Part D, each State is responsible for funding a significant portion of the drug costs of their "dual eligible" beneficiaries (i.e., low-income elderly and disabled individuals who qualify for both Medicaid and Medicare benefits) whose drug benefit was transferred from Medicaid to Medicare Part D as part of the MMA legislation.

172. The States pay their mandatory portion of Part D drug spending via monthly transfers, known as "Phase Down" or "Clawback" payments. By law, these State "Clawback" payments cover 35-40% of Part D LIS Subsidy costs each year of the Part D program.

173. Driven by the massive Part D drug price inflation for "specialty" drugs, directly resulting from this "service fee" scheme, State annual Clawback" payments have increased sharply since the start of Medicare Part D. As per the Medicare Trustee reports, State "Clawback" payments have increased from $5.5 billion in 2006 to $10.0 billion in 2016, with cumulative State payments of $80.7 billion through the latter year. State "Clawback" payments are forecasted to be $12.0 billion in 2018 and $22.5 billion by 2026. 2017 Medicare Trustees Report, July 2017.

174. Due to the brand price inflation statutes in Medicaid, these State "dual-eligibles" would have access to "old" Manufacturer Defendant drugs at a fraction of the cost, if not for the Part D pricing scheme.

175. The "old" Manufacturer Defendants drugs in this case, including Amgen's Enbrel, Eli Lilly's Humulin and Pfizer's Viagra, are currently available at 80-90% discounts to the prices in Medicare Part D.

176. As such, the "kickbacks" and federal false claims submissions related to the Manufacturer Defendant drugs have led directly to widespread financial fraud at the State level.

THE RECENT INCRIMINATING PhRMA INDUSTRY REPORT

177. In a November 2017, nearly four years after our initial Qui tam filing, the Pharmaceutical Research and Manufacturers Association (PhRMA), the leading pharmaceutical lobbying organization, released a report, entitled "Follow the Dollar".

178. While the purpose of the report was to shift blame for severe US drug prices towards its collusive PBM Defendant partners, the document definitively incriminates both parties in the systemic "service fee" scheme.

179. In the report, PhRMA, for the first time, disclosed average contract terms for "service fees" between biopharmaceutical manufacturers and the dominant PBM Defendants.

180. Of note, the individual "service fee" contracts between the Manufacturer and PBM Defendants remain a closely guarded secret, obtainable by the non-insider Relator only via discovery.

181. PhRMA is funded and controlled by the major biopharmaceutical companies. Current board members of PhRMA include Jeffrey R. Stewart (President, US Commercial Operations for Defendant AbbVie), Robert A. Bradway (CEO of Defendant Amgen), Olivier

Brandicourt (CEO of Defendant Sanofi), Vasante Narasimhan (CEO of Defendant Novartis), Ian Read (CEO of Defendant Pfizer) and David Ricks (CEO of Defendant Eli Lilly).

182. In the November 2017 report, PhRMA disclosed that the PBM Defendants and their specialty pharmacy subsidiaries receive an average of 8% of the "list" (WAC) drug price, inclusive of all price increases, for each US private insurance patient treated with a high-cost "specialty" drug in the US, such as the rheumatoid arthritis (Humira and Enbrel) and cancer (Gleevec, Tasigna, Sprycel) drugs in this case.

183. For "traditional" US pharmaceutical products, such as Defendant Pfizer's products, the PBM Defendants typically receive 4% of the "list" WAC price as "service fees" from drug manufacturers.

184. Furthermore, straightforward calculations from the report indicate that the PBM Defendants currently garner about 90-100% of their profits for "specialty" brand drugs from these manufacturer "service fees", with almost all of the remainder from "retained" manufacturer "rebates".

185. For "traditional" brand drugs, the PBM Defendants obtain about 70% of profits from "service fees", with almost all of the remainder from "retained" manufacturer "rebates".

186. To this day, the majority of independent pharmaceutical and PBM experts still publicly cite "manufacturer rebates" as the primary source of PBM Defendant profits, despite the claim being false for more than a decade.

187. As per the report, overall compensation from drug manufacturers, from combined "fees" and "rebates", accounts for 98% of PBM Defendant profits for each "specialty" drug treated patient in the US private insurance market.

188. Notably, the "8% of sales" "specialty" contract rate, disclosed by PhRMA, is

double the conservative 4% contract terms estimate in our prior Qui Tam Complaints.

189. Based upon this disclosure, and ongoing massive Defendant drug price inflation, we have greatly escalated our estimates for the direct "service fee" fraud payments to the PBM Defendants related to the "specialty" drugs in this case; namely Amgen's Enbrel, AbbVie's Humira, Novartis' Gleevec, Novartis' Tasigna and Bristol-Myers Squibb's Sprycel.

190. These private insurance calculations from the PhRMA report likely significantly understate the contribution of manufacturer "service fees" to PBM Defendant profits in the private insurance market, but especially regarding Medicare Part D.

191. In the report, PhRMA claimed that 20% of the "manufacturer fees" are "passed on" to private insurance clients. However, our discussions with highly-experienced independent PBM consultants uniformly indicate that these "manufacturer service fees" are virtually never shared with private insurance clients.

192. In fact, the PBM consultants stated that they had never negotiated a client contract with a leading PBM, in which **ANY** "manufacturer fees" were shared with one of their private insurance clients. Furthermore, the PBM consultants stated that they had never seen or reviewed a single "service fee" contract between a PBM and a drug manufacturer.

193. This PBM consultant feedback is consistent with PBM Defendant CVS Health's public disclosures. Regarding a Maryland state contract discussed in detail later in the Complaint, CVS Health publicly admitted that it "does not disclose to its clients detailed information regarding service fees (from manufacturers) received and does not share those fees with its clients." Before the Maryland State Board of Contract Appeals, Docket Nos. MSBCA 2544, 2548 & 2565, March 2007.

194. In its report, PhRMA estimated overall rebates of about 25% from manufacturers

off "list" prices and that the PBM/specialty pharmacy typically keeps about 20% of the amount.

195. However, in recent public commentary, the senior management of both Express Scripts and CVS Health stated that the company's keep only about 10% of overall manufacturer rebates. They further stated that for large private insurance clients, they often don't keep any rebates.

196. As stated by Express Script's CEO, Tim Wentworth: "It's important to understand how rebates flow. We retain 10% of rebates for our services and administrative fees, and 90% flows straight through to the plans." Forbes Healthcare Summit, New York City, November 30, 2017.

197. Since BFSFs cannot be "passed on" in government drug programs, the PhRMA report's claim of sharing 20% of "legitimate" fees with private clients is irrelevant in the Part D program.

THE RECENT INCRIMINATING PCMA INDUSTRY REPORT

198. In June 2017, the Pharmaceutical Care Management Association (CMA), the leading PBM industry lobbying organization, released a report, entitled "Increasing Prices Set by Drugmakers Not Correlated with Rebates".

199. The purpose of the report was to shift blame for severe US drug prices towards the biopharmaceutical industry. However, combined with the above PhRMA report, the PCMA report definitively incriminates both Defendant parties in the "service fee" scheme.

200. PCMA is funded and controlled by the dominant PBM Defendants. Current board members of PCMA include Tim Wentworth (CEO of Defendant Express Scripts), William Fleming (President, Health Services for Defendant Humana), Chris Hocevar (President, Strategy, Segments and Solutions for Defendant Cigna), Randy Hyun (President Pharmacy Management for

Defendant Aetna), John Prince (Chief Executive Officer of the OptumRx PBM subsidiary of Defendant UnitedHealth Group) and Jon Roberts (Executive Vice President and Chief Operating Officer of Defendant CVS Health).

201. First, the report corroborated that the PBM Defendants standardly "retain" only a small portion of "manufacturer rebates"; only in the 10% range, and less for many larger private insurance clients.

202. As per Mark Merritt, the President and CEO of the Pharmaceutical Care Management Association (PCMA), in the press release accompanying the report: "PBMs are hired by America's largest, most sophisticated, health purchasers to reduce costs by, among other things, promoting generics and negotiating rebates and discounts on brand-name drugs. Typically, PBMs pass along 90 percent or more of these savings to plans, which use them to cut premiums, out-of-pocket costs and other expenses. Many health purchasers require PBMs to pass through 100 percent of rebates." PCMA Press Release, June 12, 2017.

203. In their analysis of the "Top 200 Brand Drugs", the PCMA found no correlation between increasing drug prices and the magnitude of "manufacturer rebates"

204. In fact, PCMA reported that "Drugmakers raise prices even when rebates are low in major drug categories".

205. Specific to this case, PCMA reported that "rheumatoid arthritis drugs (DMARDs) have high price increases, yet rebates on these drugs are low".

206. As per PCMA, between 2011 and 2016, despite a 125% increase in WAC cost, "rebate levels for these drugs was only 11%" throughout the six year period.

207. In this action, our fraudulent sales estimates for the rheumatoid arthritis drugs, AbbVie's Humira and Amgen's Enbrel, are severe due to their wide use and massive uniform price

increases.

208. We estimate cumulative fraudulent US Humira and Enbrel sales of $32 billion and $19 billion, respectively, since 2006, with about 30% in Medicare Part D.

209. In concluding the report, PCMA even proposed a rationale for the vast manufacturer price increases: "Perhaps to counter shrinking prescription volume for brand drugs".

210. The PCMA report makes no mention of PBM Defendant compensation from drug manufacturers related to the vast "specialty" drug price increases - from "rebates" , "service fees" or any other sources.

211. The straightforward math from the PhRMA and PCMA reports verifies the fraudulent participation of both Defendant parties in the "service fee" scheme.

212. With the PBM Defendant only keeping about 10% of low (11%) manufacturer Humira and Enbrel discounts, PBM Defendant compensation from "retained" rebates has remained very low despite massive price increases.

213. On the other hand, PBM Defendant compensation from "service fees", which are typically all kept by the PBM, has secretly and intentionally skyrocketed along with the massive price increases.

SECRETIVE PBM DEFENDANT PARTNERSHIPS

214. Inter-relationships of the PBM Defendants also increase complexity and decrease transparency. The PBM Defendants United Healthcare, Humana, Express Scripts and CVS Health have full ownership of the PBMs/specialty pharmacies servicing the Part D plans. However, various secretive partnerships among the PBM Defendants further increase concentration and limit disclosure regarding PBM practices in both Part D and the private insurance sector.

215. In plans sponsored by Defendants Aetna and Cigna, pharmacy benefits are provided

via long-term contractual arrangements with CVS Health, and UnitedHealth Group, respectively. UnitedHealth Group took over the Cigna contract upon its acquisition of the PBM Catamaran in 2015.

216. Recent merger announcements will further increase the concentration, and decrease transparency, in the US PBM/specialty pharmacy marketplace. In December 2017, CVS Health announced its intention to acquire Aetna, Inc. In March 2018, Cigna announced its intention to acquire Express Scripts. These transactions will only escalate already severe systemic "service fee" and US drug pricing abuse.

217. According to SEC filings and management commentary, Aetna and Cigna appear to have maintained a significant amount of control over PBM functions in their contractual arrangements with larger PBM Defendants, especially regarding key formulary decisions and manufacturer contract negotiations.

218. As such, Defendants Aetna and Cigna are knowingly participating in and benefiting from the "service fee" scheme in these contractual arrangements. However, public disclosure regarding these contractual arrangements between the PBM Defendants has been minimal. Close scrutiny of the financial terms and transactions related to these secretive arrangements will be a key part of case discovery. Following is a review of the limited public disclosure regarding the PBM Defendant partnerships.

219. According to the July 27, 2010 press release, Aetna stated: "Aetna and CVS Caremark today announced they have entered into a 12-year contract to provide Pharmacy Benefit Management (PBM) services that will further enhance value and services for Aetna's customers and members. Aetna will retain its PBM and manage clinical programs, protocols and oversight of its pharmacy benefit operations…In addition, CVS Caremark will manage purchasing,

inventory management and prescription fulfillment for Aetna's mail-order and specialty pharmacy operations." The impact on this contractual arrangement of the proposed CVS Health acquisition of Aetna remains unclear.

220. As per its 2014 10-K filing, Cigna states: "In June 2013, we entered into a ten-year pharmacy benefit management services agreement with Catamaran Corporation. Under this agreement, we utilize Catamaran's technology and services platforms, retail network contracting and claims processing."

221. Catamaran's 2014 10-K further states: "The two organizations are partnering on sourcing, fulfillment and clinical services. The partnership combines Cigna's significant clinical management and customer engagement capabilities with Catamaran's innovative technology solutions, while seeking to leverage the two companies' scale of network choice and efficient procurement to deliver value to Cigna's clients and members."

222. Most indicative of Cigna's ongoing central PBM role, Catamaran stated: "The gross profit percentage related to the Cigna contract is significantly lower than historical gross profit percentages due to the related transaction volume." The lower profits for UnitedHealth/Catamaran suggest that Cigna is actively participating in the “service fee” scheme, the primary source of PBM profits.

223. In contrast, the long-term contract between Express Scripts and Anthem is apparently financially unfavorable for the latter. We suspect that Express Scripts is gaining most of the financial benefit from manufacturer “service fees” in this contract. At present, Express Scripts and Anthem are in litigation and the latter has already announced its intention not to renew the partnership. Due to these developments, we have removed Anthem as a Defendant in this Qui Tam case.

224. Catamaran was acquired by PBM Defendant UnitedHealth Group in 2015, with minimal disclosure regarding any impact on the prior Cigna partnership. With no transparency, the impact of the proposed acquisition of Express Scripts by Cigna on the existing UnitedHealth PBM contract remains unclear.

PBM PART D PROFITS: SECRET MANUFACTURER FEES, NOT REBATES

225. The secretive reliance of the PBM Defendants on the "service fee" scheme, rather than manufacturer rebates, for profits has been verified by data from both the federal government and the Defendants themselves.

226. In fact, this key, still secretive, financial discovery was the starting point of the Relator's fraud investigation more than five years ago. We summarize here and provide more details later in the document.

227. First, a 2011 Office of Inspector General (OIG) report documented that PBMs "retained" minimal "manufacturer rebates" in Medicare Part D in the program's first three years of operation (2006-2008), despite the onset of severe systemic brand drug price increases. "Concerns with Rebates in the Medicare Part D Program". OIG HHS Report, OEI-02-08-00050, March 2011.

228. As per the OIG report, in Medicare Part D for the year 2008, PBMs "retained" only $24 million (less than 1%) of overall $6.5 billion of drug manufacturer rebates. (Emphasis added)

229. As such, by definition, the PBMs were being compensated in Part D via a pathway other than "manufacturer rebates", which was the intent of the legislation and remains the current public presumption.

230. Besides "rebates", BFSFs (i.e., "service fees") are the only other mechanisms for large financial payments from drug manufacturers to the PBM Defendants in Medicare Part D.

231. With minimal retention of Part D rebates, "services fees" became secretly and knowingly the primary source of profits for the PBM Defendants in the program.

232. Second, more recently both Express Scripts and CVS Health have disclosed that they keep only about 10% of aggregate "manufacturer rebates", which, like "service fees", are standardly contractually-based on AWP or WAC prices.

233. Third, CMS' own data documents that Medicare Part D "manufacturer rebates" have averaged about 10-15% of AWP "list" prices annually since the inception of the program. Medicare Trustee Reports. The modest Part D rebates contrast with the unverifiable large rebate claims of the Manufacturer and PBM Defendants in recent years.

234. As per another government report, the "manufacturer rebate rate" for high-cost "specialty" drugs (including the Defendant rheumatoid arthritis and CML cancer drugs) has commonly been far less than the 10-15% aggregate rate in Medicare Part D. GAO-10-242, 2010; Medicare Part D – Spending, Beneficiary Cost Sharing, and Cost Containment Efforts for High-Cost Drugs Eligible for Specialty Tier".

235. The low level of "manufacturer rebates "for several of the major "specialty" drug therapeutic categories in our Qui Tam actions was recently verified by the PBM Defendants themselves.

236. As per the previous section, the PBM Defendants themselves, via the PCMA report, verified the low level (11%) of "manufacturer rebates" for the US rheumatoid arthritis "specialty" category, including AbbVie's Humira and Amgen's Enbrel, despite ongoing massive price increases.

237. Indicative of the systemic "service fee" scheme, in addition to the rheumatoid arthritis category, the PCMA report also verified the low level of "manufacturer rebates" in the

US multiple sclerosis (MS) category.

238. According to PCMA, for six long-marketed US MS drugs, despite a 125% price increase over the period, "the weighted average rebate level for these drugs for the 2011-2016 period was 7%."

239. Based upon government data and the PBM Defendants own public disclosures, the PBM Defendants are making very little profit for "manufacturer rebates"

240. Assuming an average 10% "manufacturer rebate" and the PBM Defendant publicly-stated 10% rebate "retention rate", the PBM Defendants are keeping only about 1% of AWP-based drug product sales, on average, as "rebate" compensation.

241. In sharp contrast, the PBM Defendants are secretly obtaining far greater compensation (and the vast majority of their profits) in Part D via manufacturer "service fees", routinely linked to massive, anti-competitive drug prices and price increases.

242. Using the straightforward math from the PhRMA and PCMA reports, the PBM Defendants now secretly receive, on average, 8-to-11 times as much compensation from manufacturer "service fees" compared to "retained manufacturer rebates" for high-cost "specialty" drugs. Of course, the PBM Defendant compensation for any particular "specialty" brand drug will depend upon specific contractual terms.

243. Based upon the same PhRMA report, the PBM Defendants typically receive at least twice as much compensation from manufacturer "service fees" compared to "rebates" for "traditional" brand drugs (assuming a higher 20% rebate rate). Of course, the PBM Defendant compensation for any particular "traditional" brand drug will also depend upon specific contractual terms.

244. The comparative contractual dynamics of US "specialty" and "traditional" brand

drugs is consistent with "specialty" drugs being the primary driver of massive Part D spending and fraudulent pricing over the past decade.

245. With ongoing massive price increases, the absolute PBM "service fee" compensation has skyrocketed relative to "rebates", especially for extreme-priced "specialty" drugs.

246. We use a Defendant "specialty" rheumatoid arthritis drug, Amgen's Enbrel, to illustrate the astounding economics for both Defendant parties in this collusive "service fee" scheme.

247. The annual US patient AWP cost for Amgen's Enbrel has increased from about $18,493 at the start of Part D in 2005 to about $70,343 in mid-2018, despite declining clinical usage of the drug. See **Exhibit 1**. US Enbrel annual prescriptions have declined about 20% over this timeframe.

248. Assuming a stable 10% manufacturer rebate rate, the full annual Enbrel "manufacturer rebate" increased from $1,849/patient in 2006 to $7,034/patient in 2018. The PBM Defendants keep about 10% of the full rebate each year, or about $185/patient in 2006 and $703/patient in 2018, a $518 absolute and 4-fold increase. See **Exhibit 1**.

249. The absolute increase in PBM Defendant compensation via Amgen "service fees", relative to "retained rebates", has been magnitudes greater.

250. Using the "8% of sales" PhRMA average "specialty" contract rate, the annual PBM/specialty pharmacy "service fee" payment from Defendant Amgen would be $1,479 for each Enbrel-treated patient in 2006, rising to $5,627 per patient in 2018, a $4,148 absolute and 4-fold increase.

251. The PBM/specialty pharmacy compensation from Defendant Amgen "service fees"

for each US Enbrel-treated patient is 8-fold higher than from "retained "manufacturer rebates", both in 2005 and 2018. See **Exhibit 1.**

252. "Service fees" from Amgen account for about 90% of PBM Defendant profits from Enbrel, with "retained" rebates comprising virtually all of the remainder.

253. Of course, the "service fee" financial benefit for the PBM Defendants from the scheme pales in comparison to the gains for Amgen from the massive price increases.

254. The net annual US revenues to Amgen for each Enbrel-treated patient (after rebates and fees) rises from about $15,164 in 2006 to $57,681 in 2018, a $42,517 absolute and 4-fold increase. See **Exhibit 1**.

Exhibit 1

Medicare Part D: PBM Defendant "Service Fee" vs. "Rebate" Compensation
Amgen's Enbrel

	2006	2018	Change 2006-2018
AWP Cost/Patient/Year ($)	**$18,493**	**$70,343**	**$51,850**
Estimated Amgen Rebate Rate	10%	10%	
Total Amgen Rebate ($)	$1,849	$7,034	
PBM Defendant Rebate Retention Rate	10%	10%	
PBM Defendant "Retained" Rebates ($)	**$185**	**$703**	**$518**
PBM Defendant "Service Fee" Rate	8%	8%	
PBM Defendant "Fee" Retention Rate	100%	100%	
PBM Defendant "Retained" Fees ($)	**$1,479**	**$5,627**	**$4,148**
Amgen US Revenue/Enbrel Patient ($)[1]	**$15,164**	**$57,681**	**$42,517**

[1]Excludes some other potential revenue offsets, especially drug assistance programs.

Source: Redbook/Truven, CMS, PhRMA.

255. Since PBM Defendant "manufacturer rebates" for oral cancer "specialty" brand drugs are absent or minimal in most instances, the "service fee" scheme is particularly severe for the oral CML therapies.

256. We use Novartis Gleevec to illustrate the surging economics for both Defendant parties fueled by massive price increases.

257. The annual US AWP patient cost for Novartis' Gleevec has increased from about $38,572 in 2006 to the $147,788 in 2015, just prior to its early 2016 US patent expiration.

258. In this illustration, we assume no "manufacturer rebates" for Gleevec, with all PBM Defendant compensation via "service fees". Of note, the GAO report mentioned previously (GAO-10-242, 2010) disclosed that Novartis provided no Part D rebates for Gleevec for the years 2006 through 2008, despite large price increases.

259. Using the "8% of sales" PhRMA average "specialty" contract rate, the annual PBM/specialty pharmacy "service fee" payment from Defendant Novartis would be $3,086 per Gleevec-treated patient in 2006, rising to $11,823/patient in 2015, a $8,737 absolute and more than 4-fold increase.

260. The "service fee" gains for the PBM Defendants paled in comparison to the financial gains for Novartis from the massive Gleevec price increases.

261. The net annual US revenues to Novartis for each Gleevec-treated patient (after rebates and fees) rises from about $35,486 in 2006 to the $135,965 range in 2015, an absolute $100,479 increase and more than 3-fold higher. See **Exhibit 2**.

262. Similar financial dynamics apply to the newer Defendant CML drugs, Novartis' Tasigna and Bristol-Myers Squibb's Sprycel, as well as many other extreme-priced oral cancer "specialty" drugs.

Exhibit 2

Medicare Part D: PBM Defendant "Service Fee" vs. "Rebate" Compensation
Novartis' Gleevec

	2006	2015	Change 2006-2015
AWP Cost/Patient/Year ($)	**$38,572**	**$147,788**	**$109,216**
Estimated Novartis Rebate Rate	0%	0%	
Total Novartis Gleevec Rebate ($)	$0	$0	
PBM Defendant Rebate Retention Rate	10%	10%	
PBM Defendant "Retained" Rebates ($)	**$0**	**$0**	**$0**
PBM Defendant "Service Fee" Rate	8%	8%	
PBM Defendant "Fee" Retention Rate	100%	100%	
PBM Defendant "Retained" Fees ($)	**$3,086**	**$11,823**	**$8,737**
Novartis US Revenue/Gleevec Patient ($)[1]	**$35,486**	**$135,965**	**$100,479**

[1]Excludes some other potential revenue offsets, especially drug assistance programs.

Source: Redbook/Truven, CMS, PhRMA.

263. For "traditional" brand pharmaceutical drugs, such as Defendant Pfizer's portfolio, the absolute increase in "service fees" is less for each prescription relative to "specialty" drugs. However, the aggregate fraud is also severe due to the far higher prescription volume for these products.

264. We use Pfizer's Premarin, a menopausal hormonal therapy, to illustrate the financial dynamics of a "traditional" brand drug for the Defendant partners. Estrogen replacement products are among the most widely-prescribed drugs in the US market.

265. In recent years, we estimate that approximately 450,000 Americans were treated with Premarin, compared to about 115,000 with Amgen's Enbrel and 25,000 with Novartis' Gleevec.

266. The AWP cost of a daily Premarin tablet increased from $1.28 in early 2006 to $6.43 in mid-2018, a five-fold increase.

267. The annual US AWP Premarin cost/patient has thereby increased from $467 in 2006 to $2,347 in 2018, despite plummeting clinical usage.

268. Annual US Premarin prescriptions have decreased about 60-70% over the past decade, due to escalating safety concerns and wide-ranging competition.

269. Assuming a stable 20% "manufacturer rebate", the full Premarin annual "manufacturer rebate" from Defendant Pfizer increased from $102/patient in 2006 to $469/patient in 2018. The PBM Defendants keep 10% of the full rebate each year, or about $10/patient in 2006 and $47/patient in 2018, a $37 absolute increase, nearly a 5-fold increase. See **Exhibit 3**.

270. The increase in PBM Defendant compensation from Pfizer via "service fees", relative to "retained rebates", has been far greater.

271. Using the "4% of sales" PhRMA average "traditional" contract rate, the PBM Defendant annual "service fee" payment from Defendant Pfizer would be $20 for each Premarin-treated patient in 2006, rising to $94 per patient in mid-2018, a $73 absolute increase and 5-fold more.

272. Based upon these estimates, the PBM Defendant compensation from Pfizer "service fees" for each US Premarin-treated patient is about twice as much relative to from "manufacturer rebates", both in 2006 and 2018. See **Exhibit 3**.

273. "Service fees" from Pfizer account for about 70% of PBM Defendant profits from

Premarin, with "retained" rebates comprising almost all of the remainder.

274. As with high-cost "specialty" drugs, the "service fee" financial benefit for the PBM Defendants from the scheme pales in comparison to the gains for Pfizer from the massive price increases.

275. The annual net US revenues for Pfizer from each Premarin-treated patient (after rebates and fees) rises from about $389 in 2006 to the $1,783 range in 2018, an absolute $1,394 increase and also nearly 5-fold higher. See **Exhibit 3**.

Exhibit 3
Medicare Part D: PBM Defendant "Service Fee" vs. "Rebate" Compensation
Pfizer's Premarin

	2006	2018	Change 2006-2018
AWP Cost/Patient/Year ($)	**$512**	**$2,345**	**$1,834**
Estimated Pfizer Rebate Rate	20%	20%	
Total Pfizer Premarin Rebate ($)	$102	$469	
PBM Defendant Rebate Retention Rate	10%	10%	
PBM Defendant "Retained" Rebates ($)	**$10**	**$47**	**$37**
PBM Defendant "Service Fee" Rate	4%	4%	
PBM Defendant "Fee" Retention Rate	100%	100%	
PBM Defendant "Retained" Fees ($)	**$20**	**$94**	**$73**
Pfizer US Revenue/Premarin Patient ($)[1]	**$389**	**$1,783**	**$1,394**

[1]Excludes some other potential revenue offsets, especially drug assistance programs.

Source: Redbook/Truven, CMS, PhRMA.

DETAILS OF THE FRAUDULENT "SERVICE FEE" SCHEME

276. This long-standing, centralized fraudulent pricing scheme, which began from the outset of Medicare Part D, originated from the unique financial incentives regarding rebates and BFSFs incorporated into the program.

277. In Part D, all rebates and discounts provided by drug manufacturer are deducted from "negotiated prices" and serve to lower program and beneficiary drug costs. In sharp contrast, BFSFs are the only major financial item excluded from "negotiated price" determinations in Part D.

278. These shifting disclosure and financial incentives in Part D, which began now more than 15 years ago, were seismic for both the pharmaceutical and PBM industries. However, prior to our Qui Tam Complaints, the public and most health care experts remained unaware.

279. Compounding the abuse, CMS places no restrictions on the amount of BFSFs in Part D and initially placed no BFSF reporting requirements on manufacturers and PBMs, despite documented government concern regarding potential fraudulent abuse.

280. As stated by CMS in 2012: "We continue to be concerned that these fees could be used as a vehicle to provide discounts, as opposed to fees at 'fair market value' for bona fide services." Federal Register, Vol 77, No 22, February 2, 2012.

281. Without sufficient regulatory controls or oversight, nor Part D protection from brand drug price inflation (unlike with Medicaid), the Defendant parties have advanced this BFSF scheme to a staggering magnitude in the first 12-plus years of the program's existence.

282. Further indicative of long-standing collusion and intent, our investigation determined that the Defendants quickly and secretly first began transitioning to the "service fee" model in the private health insurance market, starting in 2003 with the legislative passage of Medicare Part D, three years before it went into effect in January 2006.

283. This seismic profit model transition is reflected in the 2003-2011 10-K filings of Medco Health Solutions, the largest US PBM prior to its 2012 merger with PBM Defendant Express Scripts. The Medco filings are discussed in greater detail later in the Complaint.

284. According to the Part D regulations, legitimate patient and product support-related BFSFs paid by the Manufacturer Defendants to the PBM Defendants in Medicare Part D should be based upon drug and patient utilization.

285. As per the Code of Federal Regulations (CFR) at Sections §423.514 and §423.514 entitled "Reporting requirements for pharmacy benefit manager data": "Each entity that provides pharmacy benefits management services must provide to the Part D sponsor, and each Part D sponsor must provide to CMS, in a manner specified by CMS, the following: (4) The aggregate amount and type of rebates, discounts or price concessions (excluding bona fide service fees as defined in §423.501) that the PBM negotiates that are attributable to patient utilization under the plan". (Emphasis added)

286. Rather than linking BFSF payments to drug/patient utilization and legitimate FMV assessment, both the Manufacturer and PBM Defendant parties have violated the FCA and the AKS, with illegitimate BFSF payments in Part D based primarily upon massive, anti-competitive price increases.

287. There are few, if any, “legitimate” or “bona fide” services solely related to a drug’s price or massive drug price increases, with the possible exception of patient financial assistance programs (PAPs). Of course, the meteoric increase in financial assistance programs has been essential for advancing this price inflation scheme and deflecting public scrutiny.

288. Part D regulations and legal case precedents have established that all BFSF payments must be paid at "fair market value" (FMV) commensurate with an “arm’s length

transaction between unrelated parties".

289. By law, drug manufacturers bear the primary legal responsibility for the legitimacy of BFSFs, based upon the "Four-Part Test". 71 Fed. Reg. 69624, 69667-9.

290. By law, in Part D any "service fee" amounts paid by the Manufacturer Defendants to the PBM Defendants and other Service Vendors in "excess" of FMV must be reported to CMS as "price concessions/discounts" in DIR (i.e., "Direct and Indirect Remuneration") reports. When doing so, CMS will apply the "discount" to Part D "negotiated prices", thereby lowering drug prices for beneficiaries and taxpayers.

291. As stated by CMS in 2011: "In the case of rebate administration fees or other amounts from pharmaceutical manufacturers that exceed fair market value, but otherwise meet the definition of a bona fide service fee, the differential between the rebate administration fee or other amount and fair market value must be reported as DIR in column DIR #4." Final Medicare Part D DIR Reporting Requirements for 2010 Payment Reconciliation: Summary Report, dated June 6, 2011.

292. A lack of direct BFSF reporting requirements for drug manufacturers, PBMs and specialty pharmacies in Part D has played a key part in maintaining the secrecy of this long-standing scheme.

293. As such, we anticipate that a review of Defendant CMS Part D financial filings may not be of much value in the investigation of these allegations. For instance, with an array of inter-related subsidiaries, the PBM Defendants have many paths to obscure "fee" fraud from regulators.

294. The regulatory reporting deficiencies regarding BFSFs, especially pertaining to drug manufacturers, do not diminish the clear legal liability of the Defendant parties. According to the Part D regulations, manufacturer liability regarding the FMV determination of BFSFs is

unrelated to any CMS reporting or direct disclosure responsibilities.

295. Upon request from government authorities, particularly in a fraud investigation, drug manufacturers must provide detailed information about BFSFs, including the "itemized" services provided for individual drug products, the related payments and a legitimate FMV determination.

296. Given the Part D BFSF reporting deficiencies and the sophistication of the Defendants, a detailed review of all financial transactions between the Manufacturer Defendants and a given PBM Defendant for a particular drug product, at the corporate level, will be required in a thorough investigation.

297. As a condition of both participation and reimbursement in Medicare Part D, the Defendant corporations, their subsidiaries, as well has Chief Executive Officer (CEO) and Chief Financial Officer (CFO), must "expressly certify" against violation of both the FCA and the AKS.

298. In addition to direct "kickback" and false claims allegations, broad "express certification" adds an additional and substantial layer of liability for all the Defendants.

299. The CFR at § 423.505 (4) states: "The CEO, CFO, or an individual delegated the authority to sign on behalf of these officers, and who directly reports to the officer, must certify (based on best knowledge, information, and belief) that the information in its bids submission and assumptions related to projected reinsurance and low-income cost sharing subsidies is accurate, complete, and truthful and fully conforms to the requirements in § 423.265."

300. In § 423.505 (4), the CFR further states: "The Chief Executive Officer, Chief Financial Officer or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information provided for purposes of supporting allowable costs as defined in §

423.308 of this part, including data submitted to CMS regarding direct and indirect remuneration (DIR) that serves to reduce the costs incurred by the Part D sponsor for Part D drugs, is accurate, complete, and truthful and fully conforms to the requirements in § 423.336 and § 423.343 of this part and acknowledge that this is information will be used for the purposes of obtaining Federal reimbursement."

301. The legal liability of the PBM Defendants, either in their Part D role as plan sponsors or FDRs, has already been established by a prior Qui Tam case, the United States of America, ex. rel. Anthony Spay v. CVS Caremark Corporation.

302. The Spay case definitively established PDE submissions as a "claim for payment". Civil Action 09-4672, US District Court Eastern District of Pennsylvania.

303. As per the Spay Court Order: "The defendants' contracts with the sponsor required them to submit PDEs directly to CMS. Relying on CMS program instructions that stated that PDEs "will enable CMS to make payment," the court held that when the defendants submitted PDEs to CMS they 'clearly' were submitting 'claims' under § 3729(a)(2).'

304. Per the Spay Court Order: "the court ruled that these false statements rendered the claims false because defendants were required by 42 C.F.R. § 423.505(k)(3) to certify that the PDEs submitted to CMS were accurate, complete and truthful, and to acknowledge that the data in the PDEs would be used to obtain federal reimbursement."

305. The Defendant "percent of revenue" BFSF contracts linked to massive price increases fall outside the protection provided by either the "Group Purchasing Organization (GPO)" or the "Personal Services and Management Contracts" Safe Harbors. §1001.952.

306. These Safe Harbors require both FMV compensation and detailed disclosure to both CMS and private payers. Neither requirement has been met in these typically "secretive" BFSF

manufacturer/PBM contract arrangements.

307. The BFSF fraud among high-cost “specialty” drugs has been exacerbated by the increasing dominance of PBM Defendant centralized mail order specialty pharmacies. While the "Any Willing Pharmacy" (CFR at §423.120 (a) (8)) provision prohibits rote exclusion of independent pharmacies from Part D networks, CMS regulations do allow the PBM Defendants to offer "preferred" financial terms to their wholly-owned specialty pharmacies.

308. The PBM Defendants claim the rise of their “narrow networks” lead to lower drug prices for beneficiaries. However, the real PBM incentive for “narrow networks” is to capture the tremendous profit stream from the “service fees” associated with extreme-priced “specialty” drugs.

309. The dominance of the PBM Defendant mail order pharmacies has led to increased concentration of US “specialty” drug volume, further decreasing transparency regarding Manufacturer/PBM Defendant financial transactions.

310. Within these wholly-owned specialty pharmacies, the PBM Defendants have proprietary visibility/discretion over all pharmaceutical transactions, while limiting transparency for CMS and private payers. This unique position provides the PBM Defendants with numerous pathways to obscure the fraudulent BFSFs and other financial transactions with the Manufacturer Defendants.

311. Centralized specialty pharmacies, dominated by the PBM Defendants, now account for most of the prescription volume for the large-spending “specialty” drug categories targeted for severe BFSF fraud in the Relator's Qui Tam filings.

312. According to IMS, 86% of US multiple sclerosis drug prescriptions were dispensed by specialty pharmacies in 2014, up from 73% in 2010. In the anti-TNF inflammatory drug category, in which Defendant AbbVie’s Humira and Defendant Amgen’s Enbrel compete, 76% of

US prescriptions were dispensed by specialty pharmacies in early 2015, up from 54% in 2009. In the oral chronic myeloid leukemia (CML, cancer) category, in which Defendant Novartis' Gleevec competes, 70% of US prescriptions were dispensed by specialty pharmacies in 2014, up from 49% in 2009.

313. Driven by massive price inflation and "service fee" incentives, manufacturers and their PBM partners have little, if any, incentive to compete on price and/or aggressive rebates for market share.

314. Instead, the true battle behind the scenes is for the terms of "service fee" agreements between manufacturers and PBMs/specialty pharmacies as **ALL** products in major US brand drug therapeutic categories vastly-inflate in lockstep.

315. The dominant PBM/specialty pharmacies have considerable negotiating leverage with manufacturers, to obtain rebates and prevent price increases, in the wide-distribution, long-standing, top-spending drug categories at the center of this case, namely rheumatoid arthritis, diabetes and the CML segment of the cancer market.

316. Rather than using their leverage to garner savings for taxpayers and beneficiaries in Part D, the PBM Defendants have employed it to gain egregious "service fee" payments.

317. Beyond the Defendant products in crowded drug categories, an increasingly intense battle regarding "service fees" between manufacturers and PBMs/specialty pharmacies has also been underway in recent years regarding more unique "specialty" drugs, which typically face less competition.

318. Notable unique, extreme-priced, high revenue-generation, "specialty" drugs include AbbVie's Imbruvica (leukemia), Roche's Esbriet (pulmonary hypertension) and various other small population, extreme-cost "specialty" drugs.

319. For these "unique" products populations, manufacturers increasingly seek "limited distribution" specialty pharmacy networks. In some instances, the manufacturer may use an "exclusive" specialty pharmacy.

320. In these situations, the manufacturers have strong negotiating leverage with the PBM Defendants and smaller PBM/specialty pharmacy operators, such as Diplomat Pharmacy. To maximize profits, manufacturers seek to pay "service fees" to only a limited number of PBM/specialty pharmacies.

321. Prior to Part D, "limited distribution" drug arrangements were primarily employed for drugs that carry major safety risks, as per the FDA's Risk Evaluation and Mitigation Strategy (REMS) program. However, without any regulatory restrictions and the aberrant "service fee" incentives, "limited distribution" arrangements are now increasingly employed primarily for financial reasons.

322. Both the manufacturers and PBM/specialty pharmacies in these arrangements have a strong incentive to aggressively increase prices at the expense of their payer clients.

323. Certain "limited distribution" arrangements suggest a potential for severe "service fee"-related pricing abuse, especially for products of little clinical value and/or those dependent upon severe price increases for US-centric revenue growth. Both partners in this arrangement may be perversely motivated to vastly increase drug prices and use, rather than to prevent inappropriate spending for clients.

324. Over the past decade, the sole distribution arrangement with Express Scripts for Mallinckrodt/Questcor's Acthar suggests a high likelihood of severe "service fee" abuse. The arrangement between Questcor and Express Scripts was signed coincidently with an announced massive Acthar price increase in 2007, just after the start of Part D.

325. Acthar is an unusual product which gained a broad "grandfathered" label from the FDA, for a wide array of autoimmune indications, prior to the 1960's when the agency began requiring clinical trial proof for approval. Most expert physicians see little clinical utility for Acthar beyond a rare pediatric seizure condition.

326. Regardless, Questcor (later acquired by Mallinckrodt), with help from a dedicated "marketing" team from Express Scripts, turned the product into a billion dollar blockbuster by serially promoting Acthar for a variety of these clinically-unproven medical uses.

327. Other older "unique" specialty products that offer the potential for "service fee" abuse include Jazz Pharmaceutical's Xyrem (narcolepsy) and Mylan's Epipen (emergency allergic treatment). The primarily US-based revenue growth for both of these products has also been driven, in large part, by massive price increases.

328. Prior US Department of Justice PBM Defendant case settlements have already established negligence in the FMV of BFSFs as a basis for false claims and kickbacks.

329. On September 7, 2005, a Settlement Agreement was entered between the United States, Advanced PCS (now part of PBM Defendant CVS Health) and three Relators. In the Settlement, AdvancePCS paid the sum of $137.5 million to resolve allegations brought forth by the US government.

330. As per the Advance PCS Settlement document: "The United States alleges that…AdvancePCS allegedly solicited and/or received payments of (a) administrative fees from pharmaceutical manufacturers for services related to the negotiation and administration of rebate contracts with those manufacturers, and (b) fees for products and services agreements from pharmaceutical manufacturers…"

331. The Advanced PCS settlement document further states: "The United States also

alleges that to the extent that the payments exceeded the value of the above-referenced services and products, AdvancePCS knowingly caused false claims to be made to OPM and false Medicare claims to be made to HHS. In addition, the United States alleges that AdvancePCS knowingly caused false Medicare claims to be made to HHS in connection with soliciting and/or receiving kickbacks in the nature of payments exceeding the value of the above-referenced services and products."

332. Our investigation also indicates a high likelihood of "sham" BFSF payments (i.e. FMV equal to zero) from the Manufacturer Defendants to the PBM Defendants for services that are not actually being provided.

333. All the PBM Defendants make extensive claims regarding "clinical support" they are providing to physicians and patients, especially regarding "specialty" drugs. Common clinical support services highlighted by the PBM Defendants include injection training, patient consultations regarding drug efficacy/safety, input regarding drug selection and drug adherence programs.

334. However, extensive Relator interviews with specialist physicians uniformly indicate that the vast majority of clinical "support services" are actually being provided by office medical staff or directly by drug manufacturers, not the PBM Defendants or their affiliated specialty pharmacies.

335. The dominant role of centralized mail order pharmacies for the distribution of "specialty" drugs indicates that the PBM Defendants are greatly overstating their "clinical support services". Simply put, even for patients newly-started on "specialty" drugs, the PBM Defendants typically have minimal, if any, in-person contact.

336. Furthermore, for the vast majority of patients that are stable on chronic drug

therapy, potential PBM/specialty pharmacy "services", beyond simply mailing the prescription, are scant. Our discussions with both expert physicians and "specialty" drug-treated patients verify these findings.

337. The potential for "sham" "service fee" payments may be even greater for oral drugs, including the oral CML "specialty" drugs and Pfizer's "traditional" products in this case. For many of these chronically-administered oral drugs, our investigation suggests few legitimate "support services" are being provided by the PBM Defendants (via their remote specialty pharmacies) for the vast majority of patients, beyond simply filling and mailing the prescription.

338. While the majority of the fraudulent drug costs enabled by the Part D BFSF scheme have been borne by US taxpayers at the federal level, state drug spending fraud has also been severe.

339. Prior to 2006, low-income seniors and disabled individuals who qualified for both Medicare and Medicaid received outpatient drug benefits through state Medicaid programs. When Medicare Part D was implemented in 2006, these "dual eligible" beneficiaries began receiving drug coverage under Medicare Part D, without recourse.

340. Due to their compromised health, these "dual eligibles" accounted for 50% of Medicaid drug costs and the majority of extreme-priced "specialty" drug spending prior to the transfer, despite only comprising 13% of the Medicaid enrollment in 2005. OIE-03-10-00320, Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicaid Part D, August 2011.

341. By law, each state is required to fund about a third of Medicare Part D spending for their respective "dual eligibles" via "clawback payments" to CMS. From 2006 through 2016, states made cumulative "clawback" payments of $80.7 billion to CMS. 2017 Medicare Trustees Annual

Report, July 2017.

342. Medicaid requires additional manufacturer rebates for all annual brand price increases greater than inflation (CPI-Urban) whereas Medicare Part D provides no such protection. After many years of severe price increases, the Medicaid net cost for many brand drugs, especially older “specialty” drugs, is now a fraction of the Part D price.

343. The Relator obtained propriety information indicating that the Medicaid 2013 net cost for long-marketed “specialty” and “traditional” US brand drugs are now commonly 80-90% below the cost in Part D.

344. In its most recent comparison of Medicaid and Medicare Part D rebates, the Office of Inspector General (OIG) concluded that "the inflation-based additional rebate, meant to protect Medicaid from large drug increases in drug prices, was the primary reason that Medicaid rebates were higher than Part D rebates”. OIE-03-10-00650, Medicaid Rebates For Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin. Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicaid Part D, April 2015.

345. From the same report: “for the 200 brand-name drugs with the highest Part D expenditures in 2012, rebates accounted for 47 percent of Medicaid expenditures, whereas rebates totaled 15 percent of Part D expenditures."

346. If state "dual eligibles" had remained within Medicaid, their brand drug costs would now be a fraction of the cost in Medicare Part D. A significant portion of state "clawback" payments since the start of Part D have been driven by the “service fee” fraudulent pricing scheme.

347. Our investigation also indicates fraudulent abuse of the essential Part D plan sponsor “catastrophic” cost-sharing requirements. In Part D, plan sponsors (i.e., the insurance entities) are required to pay 15% of all drug costs above a very modest annual threshold ($3,600

in 2006, rising to $5,000 in 2018).

348. This "cost-sharing" exposure was expected to motivate plan sponsors to negotiate aggressively with manufacturers to get favorable prices for high cost "specialty" drugs. However, this essential cost-control mechanism has broken down because, in practice, the PBM Defendants (and their wholly-owned subsidiaries) surprisingly serve as the plan sponsor, PBM and specialty pharmacy for the majority of Part D plans and beneficiaries.

349. After more than a decade of massive price inflation, the PBM Defendants (in their function as plan sponsor) are responsible for about $10,000 of "catastrophic" annual drug costs for each US Part D autoimmune patient treated with Amgen's Enbrel or AbbVie's Humira.

350. At its final $150,000 annual price in late 2015 (just prior to its February 2016 patent expiry), plan sponsors would be responsible for approximately $20,000 in "catastrophic" cost-sharing for each Part D leukemia patient treated with Defendant Novartis' Gleevec.

351. The dominant PBM Defendants have similar or even greater "catastrophic" cost-sharing exposure for many other Part D beneficiaries treated with high cost "specialty" drugs, especially for cancer and hepatitis C.

352. We concluded that the Manufacturer Defendants, in many instances, are "forgiving" the PBM Defendants for this "catastrophic" exposure in order to further the "service fee" pricing scheme.

353. Without this cost-sharing "forgiveness", massive plan sponsor "catastrophic" exposure for the PBM Defendants would have led to legitimate price negotiation with the Manufacturer Defendants, preventing most, if not all, of the Defendant drug price inflation. The potential abuse of Part D "catastrophic" cost-sharing requirements appears aided by minimal Defendant CMS reporting requirements.

STAGGERING FRAUD FOR FOURTEEN DEFENDANT BRAND DRUGS

354. While the "service fee" business model is now employed systemically, this case focuses on a select group of older US "blockbuster" drugs in which the scheme has been advanced to a staggering degree.

355. For most of the Defendant drugs, the decade-plus long "service fee" scheme has yielded an astounding 4-6 fold increase in prices, despite plummeting clinical use, prescription volume and market share.

356. The 14 Defendant brand drugs are: AbbVie's Humira (arthritis/inflammatory conditions, FDA-approved 2003); Amgen' Enbrel (arthritis/inflammatory conditions, 1997), Novartis' Gleevec (cancer, 2001), Novartis' Tasigna (cancer, 2007), Bristol-Myers Squibb's Sprycel (cancer, 2006), Sanofi's Lantus (insulin for diabetes, 2000), Eli Lilly's Humulin (insulin for diabetes, 1982), as well as Pfizer's Lyrica (neuropathic pain, 2004), Viagra (erectile dysfunction, 1998), Celebrex (osteoarthritis/pain, 1998), Chantix (smoking cessation, 2006), Premarin (hormone replacement/osteoporosis, 1942), Pristiq (depression, 2008) and Relpax (migraine, 2002).

357. The extreme divergence between pricing and volume trends for these drugs is clearly indicated in **Exhibit 4**.

Exhibit 4
Massive Defendant Product Price Inflation
Eroding or Slowing Patient Use

Product (US Approval)	2006 Annual Patient Cost AWP ($)[1, 2]	2018 Annual Patient Cost AWP ($)	2006-18 Change in AWP	Percent Change in US Treated Patients [3, 4] 2006-16	2010-16
Enbrel (Amgen, 1997)	$18,493	$70,343	**3.8x**	-22%	-11%
Humira (AbbVie, 2003)	$20,920	$69,235	**3.3x**	207%	82%
Gleevec (Novartis, 2001)	$48,050	$147,788	**3.1x**	19%	-6%
Tasigna (Novartis, 2007)	$83,238	$198,854	**2.4x**	-	387%
Sprycel (Bristol, 2006)	$64,496	$188,516	**2.9x**	-	209%
Lantus (Sanofi, 2000)	$1,405	$5,903	**4.2x**	79%	28%
Humulin (Eli Lilly, 1982)	$660	$3,257	**4.9x**	-47%	-34%
Lyrica (Pfizer, 2004)	$1,517	$6,512	**4.3x**	59%	8%
Viagra (Pfizer, 1998)	$550	$3,879	**7.1x**	-58%	-42%
Celebrex (Pfizer, 1998)	$1,220	$5,282	**4.3x**	-40%	-20%
Chantix (Pfizer, 2006)	$1,402	$6,278	**4.5x**	-	-14%
Premarin (Pfizer, 1942)	$512	$2,347	**4.6x**	-	-57%
Pristiq (Pfizer, 2008)	$1,494	$5,092	**3.4x**	-	-29%
Relpax (Pfizer, 2002)	$879	$3,587	**4.1x**	-	-18%

[1] From Redbook/Truven Analytics Pricing Database.

[2] Patient cost estimates based upon average FDA-approved maintenance dose.

[3] IMS Health National Prescription Audit (NPA) database and our estimates.

[4] Gleevec data through 2015, prior to February 2016 US patent expiration; Celebrex data through 2014, prior to 2015 US patent expiration.

358. As per **Exhibit 4**, the clinical usage of all but 5 of the Defendant drugs (Humira, Sprycel, Tasigna, Lantus and Lyrica) has been in significant decline.

359. Despite the eroding clinical use, and counter to any competitive market rationale,

all these Defendant products have had massive price increases instituted by the manufacturer over the past decade.

360. None of the manufacturers has disclosed any unique factors, such as drug shortages, which could have contributed to the price increases.

361. For the 5 products with rising clinical use over the decade, vast price increases have occurred despite escalating competition from a variety of new clinically-similar drugs.

362. Further suggestive of severe anticompetitive activity, price inflation has been virtually uniform and lockstep for all drugs in the major therapeutic categories in which the Defendant products compete.

363. In the rheumatoid arthritis, diabetes and CML cancer categories, all new drugs reaching the US market over the past decade have been launched at a parity or above the prices of fast-inflating older drugs. Thereafter, all manufacturers continue to increase prices aggressively in lockstep, as the “service fee” scheme advances.

364. We provide specific details regarding the pricing trends for the Defendant products and the therapeutic categories later in the Complaint.

365. The PBM "savings" opportunity, via aggressive rebate and price negotiations, should be considerable in top-spending US therapeutic brand drug categories crowded with numerous clinically-similar drugs - i.e., such as the rheumatoid arthritis, cancer and diabetes categories at the center of this case.

366. As the scrutiny of US drug pricing has escalated, drug manufacturers have increasingly argued that they are not receiving much of the financial benefit from vast AWP “list” price increases.

367. Statements of this nature are simply untrue regarding the Manufacturer Defendant

brand drugs targeted in this case. Based on their own SEC-reported financial statements, these Manufacturer Defendants have received vast US revenue and profit gains from the massive price increases over the past decade-plus.

368. The divergent pricing trends for brand drug prices in the US and Europe clearly indicates the role of both Medicare Part D and PBMs in this domestic price inflation scheme. Of note, the PBM industry is a uniquely American industry, with a minimal presence outside of this country.

369. Prior to the arrival of Medicare Part D, the cost of the Defendant brand drugs were approximately at parity among the US and major European countries.

370. Now, more than 12 years after the arrival of Part D (administered by PBMs), the cost for these drugs is typically 4-8 fold higher in the US compared to major European countries. Massive price inflation has occurred in the US, while prices for these "old" drugs have change little in Europe.

371. For instance, as of the spring of 2017, the annual US cost of AbbVie's Humira and Amgen's Enbrel was more than 4-fold higher than in Europe. The annual US cost of Sanofi's Lantus (long-acting insulin) was 7-8 fold higher compared to Europe. Joseph Cruz, April 6, 2017.

372. The annual US cost of Pfizer's Lyrica was nearly 5-fold higher compared to major European nations. Biostrategies Analytics, March 18, 2017.

373. For these declining and competitively-challenged Defendant drug products, stable European prices indicate a properly functioning marketplace. In sharp contrast, the US market has become distorted by the systemic and fraudulent "service fee" scheme between drug manufacturers and the dominant PBM Defendants.

374. In **Exhibit 5**, we provide the contribution of price increases and utilization to SEC-

reported US sales for the 8 Defendant products that have been available since the 2006 start of Medicare Part D.

375. Most of these brands are top-spending drugs both in the private insurance market and Medicare Part D. Humira is now the top-spending drug both in the US and worldwide. Enbrel and Gleevec have been among the top 10 Part D US drugs in terms of spending for most plans over the past decade. Until recently, Lantus was the top-spending single drug in Medicare Part D.

Exhibit 5
Manufacturer Defendant US Product Sales: 2005-2017
Driven by Massive Price Increases

	2005 Reported US Sales ($mil)	2017 Reported US Sales ($mil)	2017 Sales at 2005 Prices ($mil)	Reported US Sales Growth 2005-2017	Growth Without Price 2005-2017
Enbrel (Amgen)	$2,470	$5,206	$1,892	111%	-23%
Humira (AbbVie)	560	12,361	3,809	2107%	580%
Gleevec (Novartis)[1]	524	2,533	696	383%	33%
Lantus (Sanofi)	846	4,046	1,775	378%	110%
Humulin (Eli Lilly)	411	885	173	115%	-58%
Lyrica (Pfizer)[2]	717	3,463	1,165	383%	62%
Viagra (Celebrex)[3]	796	1,148	265	44%	-67%
Celebrex (Pfizer)[4]	1,577	1,735	951	10%	-40%
Total Revenues	**$7,901**	**$31,377**	**$10,726**	**297%**	**36%**
Total Ex Humira	**$7,341**	**$19,016**	**$6,917**	**159%**	**-6%**

[1] US Gleevec sales in 2015, prior to early 2016 patent expiry.

[2] 2006 Pfizer product US sales.

[3] Viagra 2016 US sales, prior to 2017 patent expiry.

4 Celebrex 2014 US prior to 2015 patent expiry.

Source: Company Reports, Truven/Redbook and our estimates.

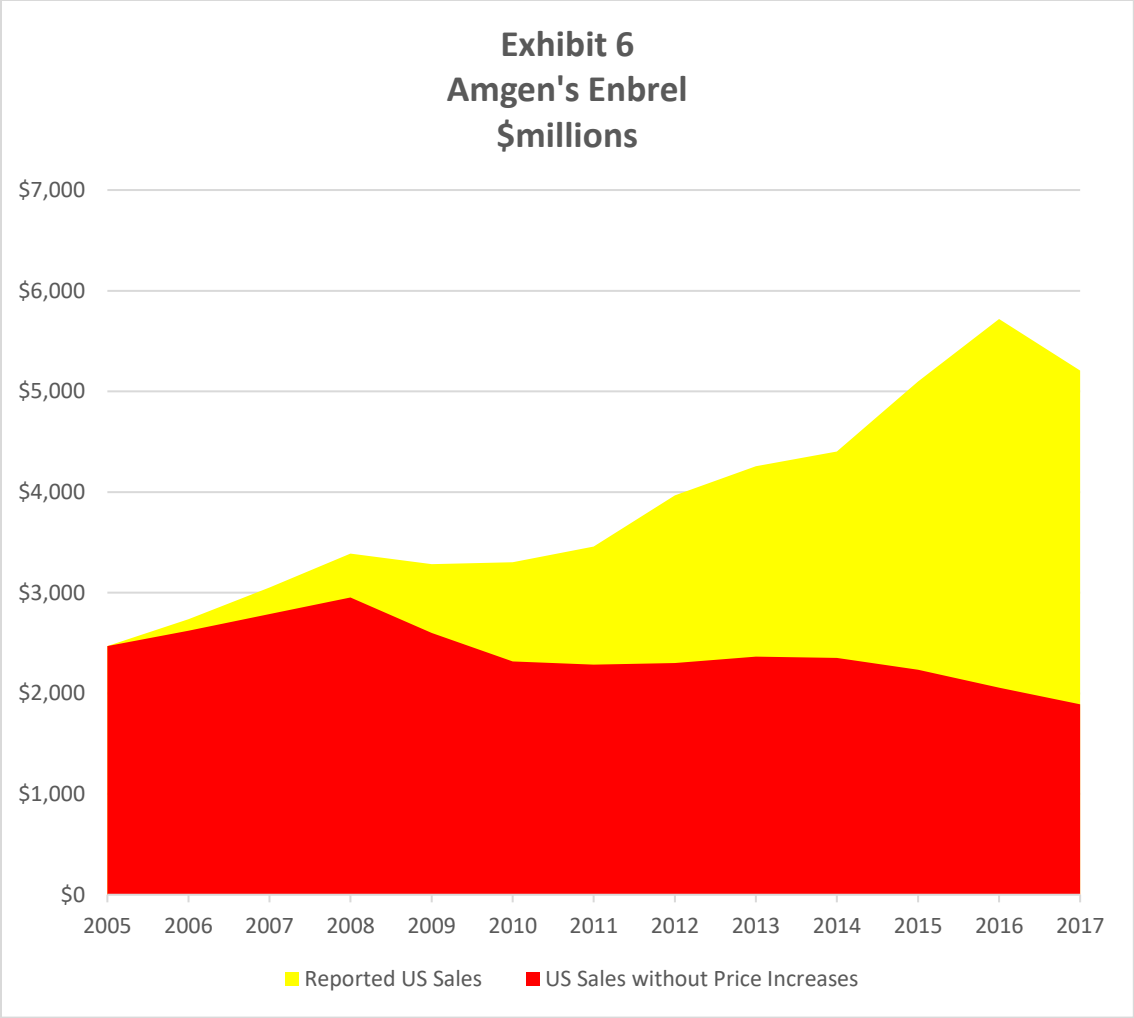
376. Based upon reported sales, public pricing data and documented utilization trends, we calculate that nearly 90% of the SEC-reported annual US revenue increase, between 2005 and 2017, for these eight major Defendant products has been driven by price increases.

377. Overall, we calculate that US sales for these 8 products would only have increased from about $7.9 billion in 2005 to about $10.7 billion in 2017, based solely on prescription volume.

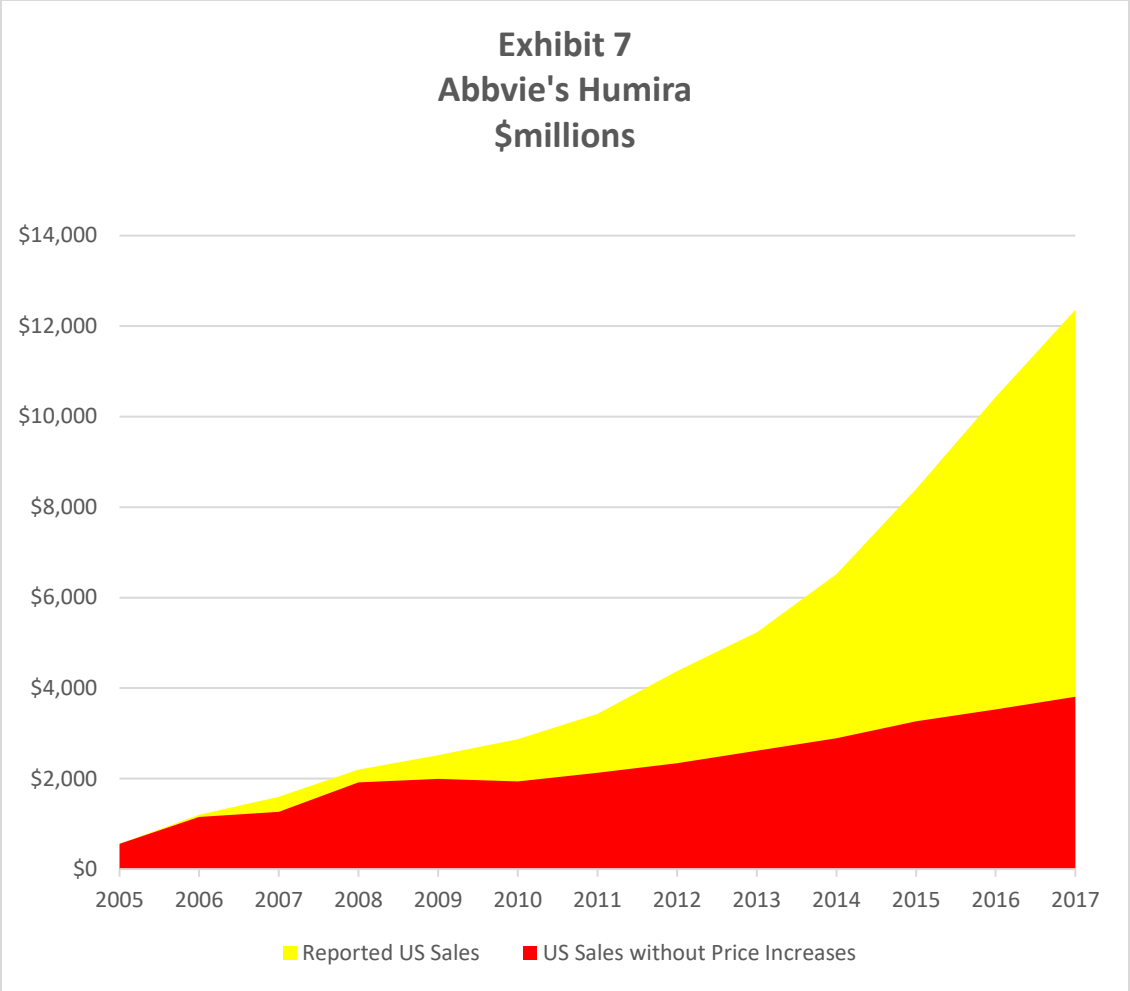
378. Instead, driven by massive price increases, the SEC-reported US sales for these products has more than tripled to $31.4 billion in 2017.

379. The staggering, cumulative US public harm over the past decade-plus is well-illustrated by the graphic contribution of price and volume to SEC-reported US sales for the major Defendant drugs.

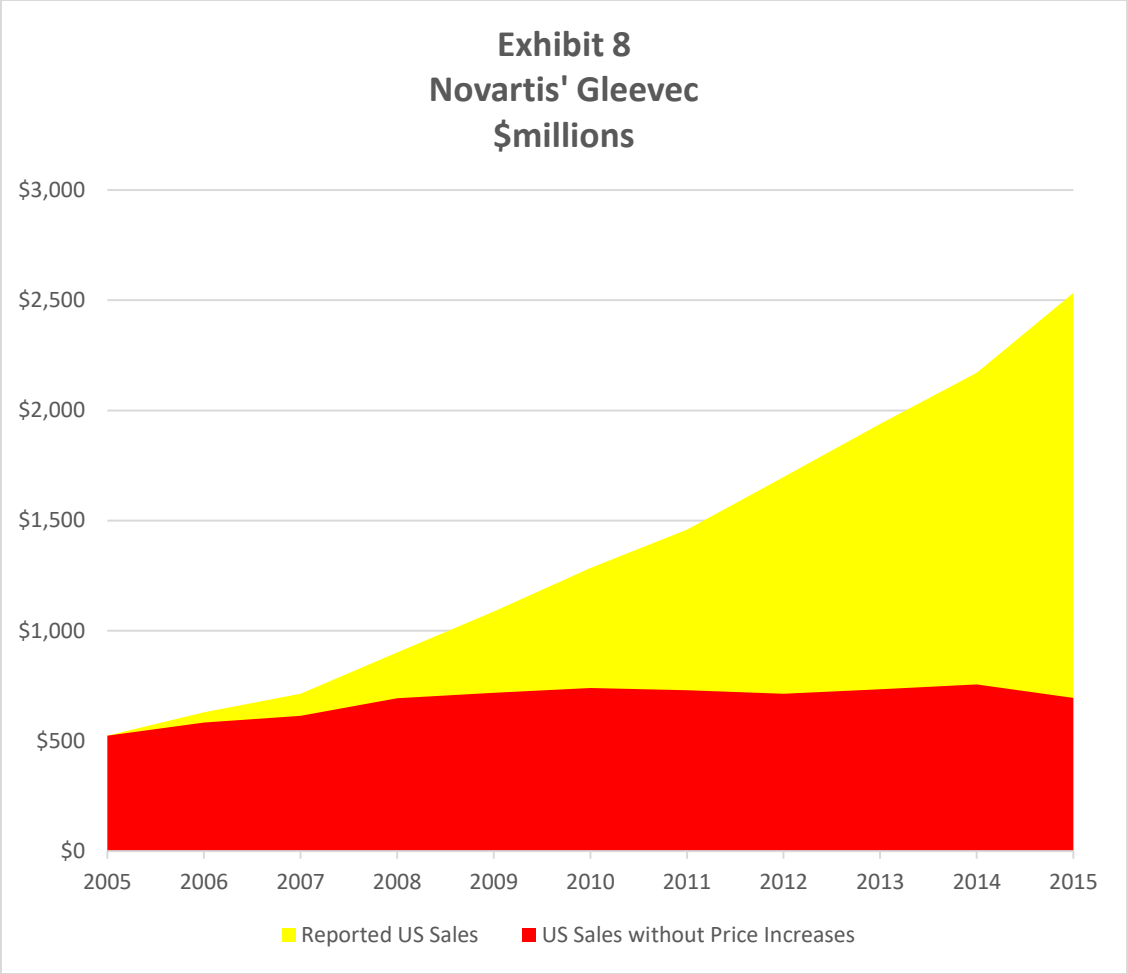
380. For Amgen's Enbrel, SEC-reported US sales increased from $2.5 billion in 2005 to $5.2 billion in 2017. The AWP annual US patient cost of Enbrel has increased from about $17,600 in 2005 to $70,000 in mid-2018. US annual prescriptions for Enbrel have decreased approximately 20% over this period. Without price increases, US annual Enbrel sales would have decreased to the $1.9 billion range in 2017. See **Exhibit 6**.



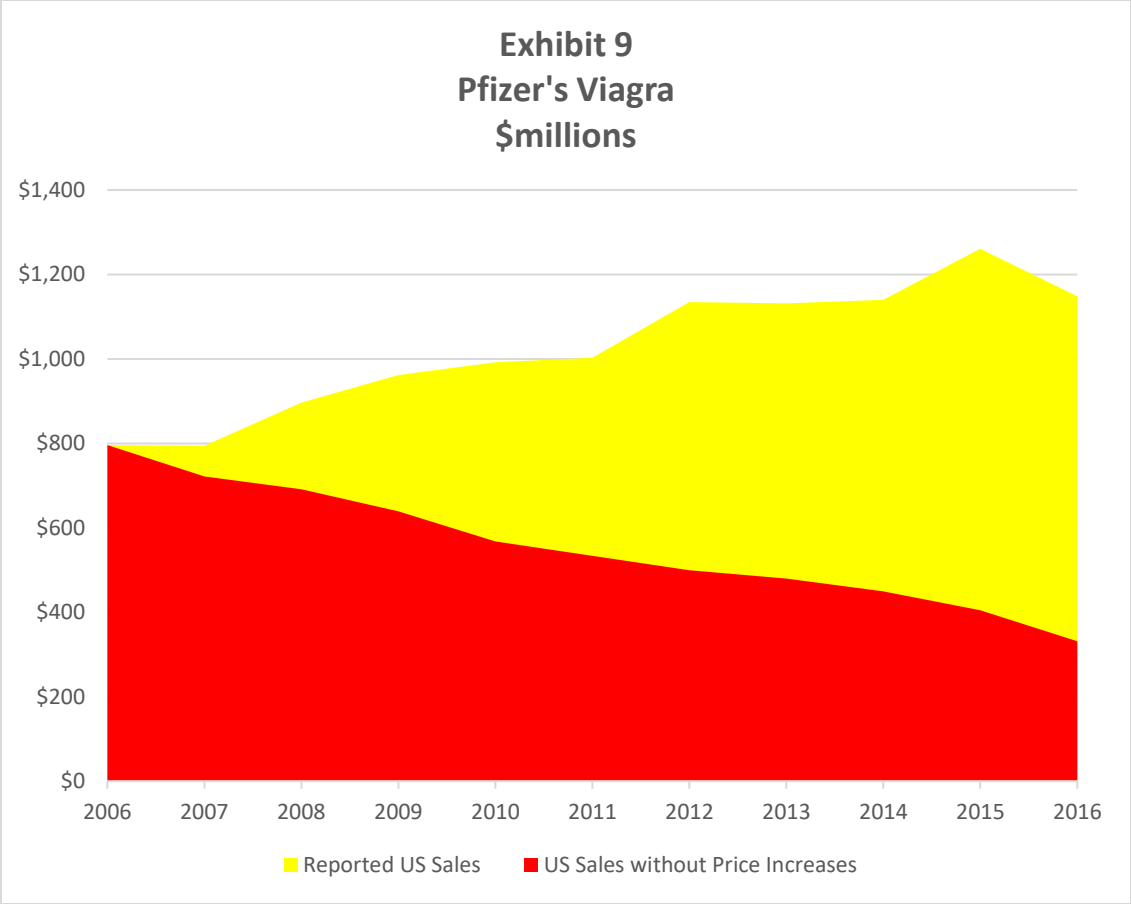
381. The absolute financial harm from vast price increases has been greatest for AbbVie's Humira due to its wide use and volume growth. Humira SEC-reported US sales have increased from about $560 million in 2005 to $12.4 billion in 2017. Humira is now the top-selling drug both in the US and worldwide. Over this time period, US Humira prices have increased in lockstep with Amgen's Enbrel, with an AWP patient/year cost of about $69,235 in mid-2018. Without price increases, US Humira sales would have only been in the $3.8 billion range in 2017, only about a third of the reported sales level. See **Exhibit 7**.



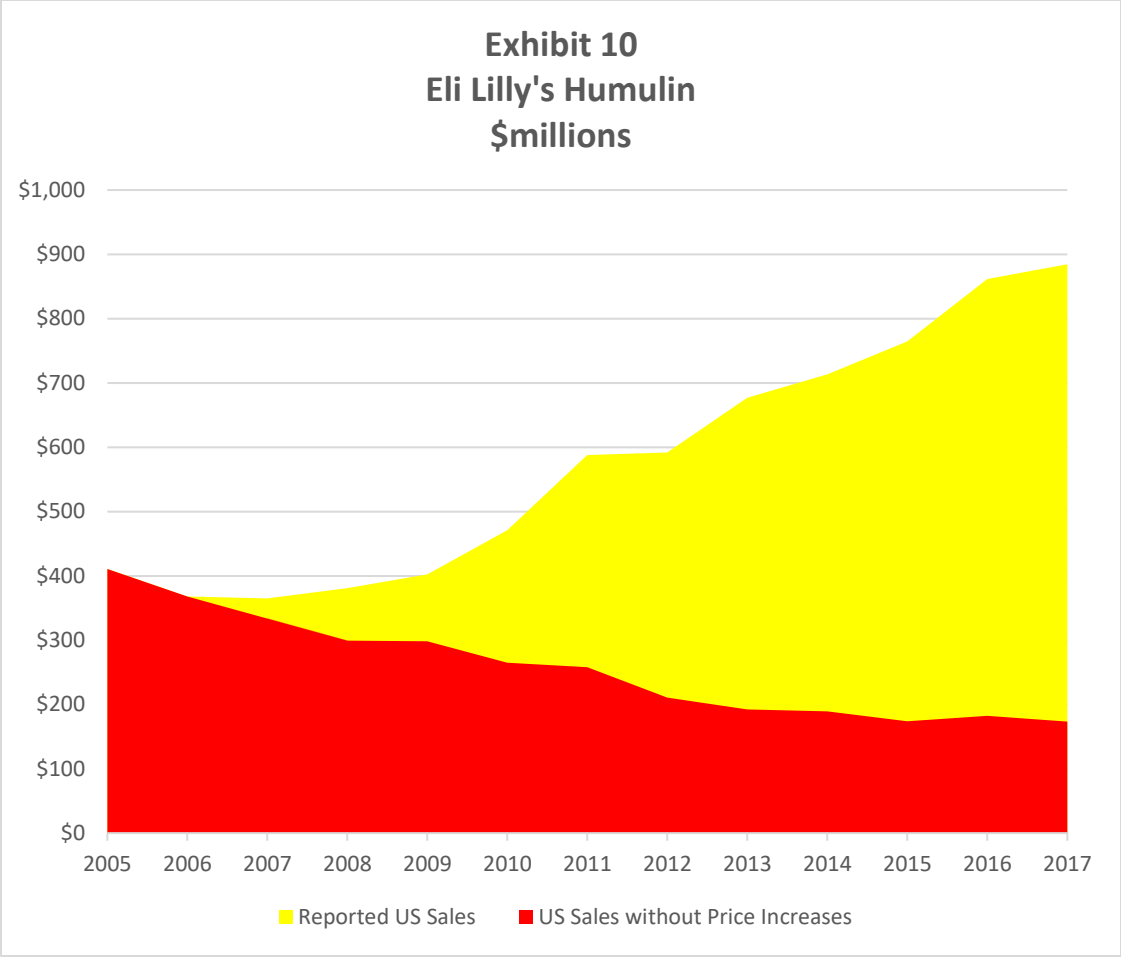
382. Novartis' Gleevec provides a startling example of pricing abuse in the US cancer market. SEC-reported US Gleevec sales rose from $524 million in 2005 to $2.5 billion in 2015, just prior to its early 2016 US patent expiration. Since the start of Part D, Gleevec's annual US prescriptions grew a modest 20%, but were in decline since 2010. The AWP annual patient cost of Gleevec has increased from about $35,200 in 2005 to $147,800 in 2015. Without price increases, 2015 US Gleevec sales would have only been in the $700 million range. See **Exhibit 8**.



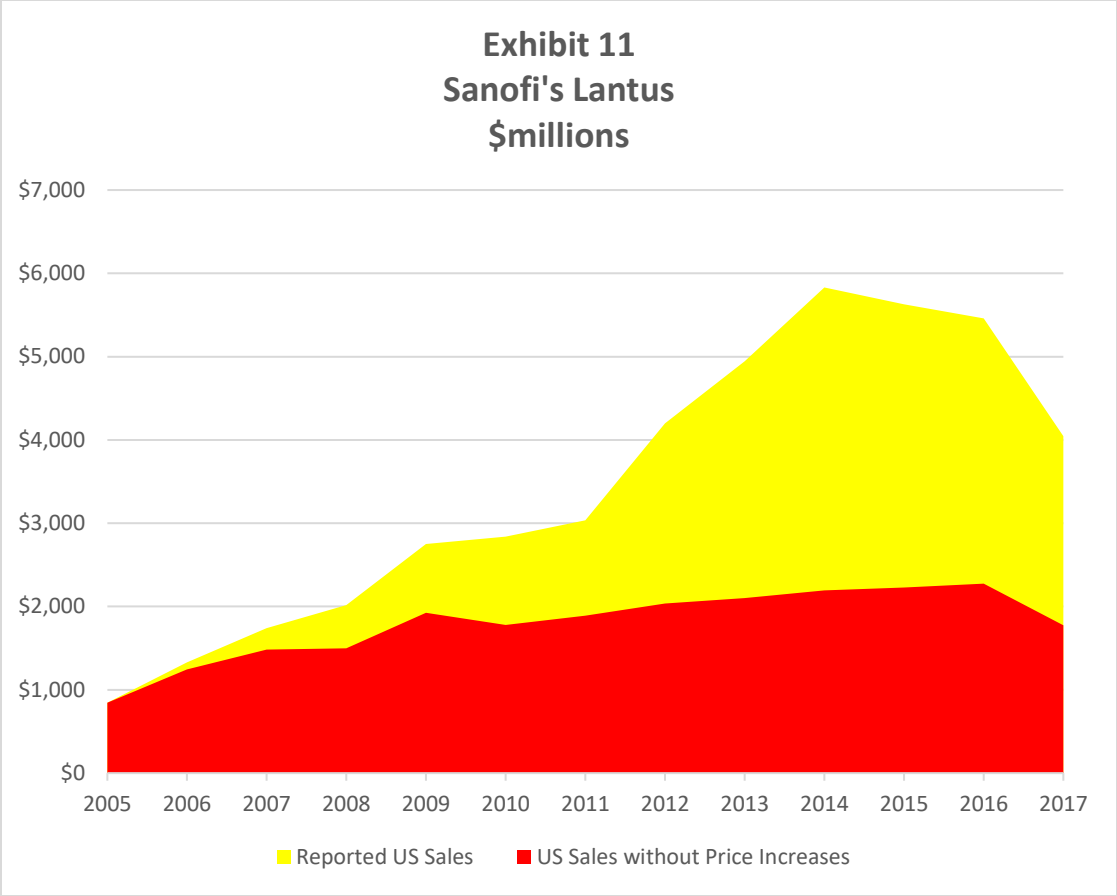
383. For Pfizer's Viagra, SEC-reported US sales rose from $796 million in 2005 to $1.15 billion in 2016. The AWP cost of each Viagra pill has increased from about $11.46 in 2005 to $80.82 in mid-2018. US annual prescriptions for Viagra have decreased approximately 40% over this period. Without price increases, US Viagra sales would have fallen to the $330 million range in 2016. Viagra's US patent expired in late 2017. See **Exhibit 9**.



384. For Eli Lilly's Humulin, SEC-reported US sales increased from $411 million in 2005 to $885 million in 2017. The AWP annual US patient cost of Humulin (for a 50 unit daily dose) has risen from about $606/patient in 2005 to the $3,260 range in mid-2018. US annual prescriptions for Humulin have decreased approximately 40% over this period. Without price increases, US Humulin sales would have fallen to the $175 million range in 2017. See **Exhibit 10**.



385. For Sanofi's Lantus, SEC-reported US sales increased from about $850 million to a peak of about $5.8 billion in 2014, before decreasing to about $4.1 billion in 2017 as scrutiny and competition in the insulin category escalated. These US sales amounts include Sanofi's Toujeo, a concentrated version of Lantus, which was FDA-approved in February 2015. The AWP annual US patient cost of Lantus (for a 50 unit daily dose) has risen from about $1,318/patient in 2005 to the $5,606 in mid-2018. Without price increases, 2017 US Lantus/Toujeo sales would have been in the $1.8 billion range in 2017, less than half of the reported amount. See **Exhibit 11**.



386. In **Exhibit 12**, we summarize the estimated "service fee" and US sales fraud, by Defendant product for the 2006-2017 period. The fraud estimates are truly staggering due to the magnitude of massive price increases and the cumulative/compounding impact of this long-standing scheme.

387. For the 14 Manufacturer Defendant products targeted in this Complaint, we estimate nearly $114 billion of cumulative fraudulent US drug sales have been enabled by the scheme between 2006 and 2017, with the fraud ongoing and escalating. We estimate that 30% of this fraud has occurred in Medicare Part D.

388. Our estimates for fraudulent Manufacturer Defendant US product sales are nearly double those from our prior October 2014 SDNY Qui Tam filing, due to ongoing, severe and

lockstep price increases for the Manufacturer Defendant brand drugs

389. We further estimate that this sales fraud has been enable by approximately $7.0 billion in fraudulent "service fee" payments from the Manufacturer Defendants to the PBM Defendants over the past decade and more. Our direct "service fee" fraud estimate is calculated using the PhRMA disclosed "service fee" contract rates of 8% and 4% "of "list" price revenues, for "specialty" and "traditional" Defendant products, respectively.

390. Our estimates for direct fraudulent "service fee" payments from the Manufacturer Defendants to the PBM Defendants have more than triple since our initial October 2014 Qui Tam filing, primarily due to the higher "8% service contract" rate for "specialty" drugs, disclosed by PhRMA. Our prior filing utilized a conservative "4% of sales" "service fee" contract rate for all Defendant drugs.

Exhibit 12
Staggering Cumulative Financial Harm: 2005-2017
Direct "Service Fee" and US Sales Fraud
($ million)

	Direct "Service Fee" Fraud ($mil)[1]	US Sales Fraud ($mil)	Estimated Part D Market Share (%)
Enbrel (Amgen)	$1,528	$19,105	30%
Humira (AbbVie)	2,585	32,308	30%
Gleevec (Novartis)	542	7,436	60%
Tasigna (Novartis)	113	1,023	60%
Sprycel (Bristol-Myers)	199	2,514	60%
Lantus (Sanofi)	855	21,384	30%
Humulin (Eli Lilly)	165	4,124	30%
Lyrica (Pfizer)	395	9,885	30%
Viagra (Pfizer)	227	5,670	20%
Celebrex (Pfizer)	170	4,262	35%
Chantix (Pfizer)	61	1,525	15%
Premarin (Pfizer)	109	2,725	30%
Pristiq (Pfizer)	51	1,264	25%
Relpax (Pfizer)	17	421	15%
Total	**$7,017**	**$113,647**	

1 Using 8% PhRMA "specialty" drug average "service fee" contract rate.

Source: Corporate reports, PhRMA, Redbook/Truven, our estimates.

391. Our cumulative estimates of US sales fraud for the individual Manufacturer Defendant drugs are similarly staggering.

392. As the top-selling product in the US and worldwide, the US sales fraud estimate is greatest for AbbVie's Humira, at more than $32 billion between 2006 and 2017. Close behind are the fraud estimates for Enbrel and Lantus, at $19 billion and $21 billion, respectively.

393. However, the sales fraud estimates are also large for other Defendant drugs, due to their severe fraudulent price inflation over more than a decade.

394. In this action, we seek restitution for the massive overpayment of Part D drug costs and "service fees" generated by this systemic price collusion scheme, plus treble damages.

EVIDENCE OF SEVERE PART D CATASTROPHIC "COST-SHARING" FRAUD

395. The escalating "service fee" scheme for extreme-priced "specialty" drugs has also fueled severe financial fraud regarding essential Part D plan sponsor "catastrophic" cost-sharing requirements.

396. The evidence of "catastrophic" abuse has particularly escalated in the recent years, with the annual patient cost of "specialty" drugs now routinely in the $70-200,000 or more price range.

397. In Part D, taxpayers (via the Part D "Reinsurance Subsidies") cover 80% of all drug costs for any beneficiary crossing a modest annual "catastrophic threshold", which was $3,600 in 2006 and rose to $5,000 in 2018.

398. For extreme-priced "specialty" drugs, typically with an annual treatment cost now in the $70-200,000 range ($5,000-16,700 or more per month), most treated Part D patients now cross the "catastrophic threshold" in the first 1-2 months of each calendar year.

399. In order to incentivize aggressive price negotiation with manufacturers, Part D requires plan sponsors to cover an unlimited 15% of all "catastrophic" spending for beneficiaries.

400. This "cost sharing" requirement is the central Part D mechanism to incentivize cost control and legitimate negotiation with drug manufacturers regarding extreme-priced "specialty" drugs in the program.

401. However, as noted previously, since the PBM Defendants serve all three key

functions (plan sponsor, PBM and specialty pharmacy) for the majority of Part D plans and beneficiaries, this "independent" plan sponsor function has been compromised.

402. The failure of this essential cost-control mechanism is indicated by the vast increase in Part D "catastrophic" spending in recent years.

403. Massive unanticipated "catastrophic" over-spending has been the primary driver of accelerating Part D spending in recent years. In 2016, Part D "catastrophic" spending was $34.8 billion, up more than 3-fold just since 2010 and from only $6 million in 2006.

404. "Catastrophic" spending accounted for less than 15% of Part D spending in 2006, rising to 38% of program spending in 2016. According the 2017 Medicare Trustees Report, "catastrophic" spending is forecasted to be $42.1 in 2018 and more than $80 billion by 2026, remaining the primary driver of Part D spending growth.

405. The "catastrophic" overspending in recent years has been fueled by the massive inflation of older "specialty" drugs, as well as the broad Part D use of new hepatitis C therapies and extreme-priced cancer drugs.

406. In a properly-functioning marketplace, this excess spending should have placed an extreme financial burden on Part D plan sponsors, including the dominant PBM Defendants.

407. A MedPAC report from June 2015 indicated that plan sponsors had under-forecasted Part D "catastrophic" spending by more than $6 billion in 2013 (or by more 50%) of the actual "catastrophic" spending of $19 billion for the year. MedPAC Report to Congress: Medicare and the Health Care Delivery System, June 2015, Chapter 6, "Sharing Risk in Medicare Part D".

408. Consistent with their dominant plan sponsor role in the Part D program, in the MedPAC report 70% of the unforeseen "catastrophic" spending was attributed to the four largest

PBM Defendants, Express Scripts, CVS Health, UnitedHealth Group and Humana.

409. At the 15% cost-sharing rate, the $6 billion in excess Part D "catastrophic" spending in 2013 corresponds to unforeseen plan sponsor additional "cost-sharing" exposures of more than $900 million just for that single year for all plan sponsors and about $630 million for the four largest PBM Defendants.

410. Furthermore, the bid, premium and actual "catastrophic" spending data suggest a further marked acceleration in unforeseen plan sponsor "cost-sharing" for 2014 and 2015.

411. Aggregate plan sponsors forecasted a 40% increase in Part D "catastrophic" spending between 2013 and 2015. The actual 2015 "catastrophic" spending came in at $33.2 billion, 73% higher than 2013.

412. We estimate Part D plan sponsors (i.e., primarily the PBM Defendants) underestimated combined 2014 and 2015 "catastrophic" spending by another $10 to $20 billion.

413. This additional program spending led to an estimated $1.5 to $3.0 billion in unforeseen "cost sharing" expenses for aggregate Part D plan sponsors for 2014 and 2015 combined, with the four largest PBM Defendants responsible for about $1.1 to $2.1 billion.

414. Despite this large unforeseen "cost-sharing" burden, all the PBM Defendants have reported robust financial results for 2013-2015 and none has indicated significant financial challenges in Part D.

415. This fact is inconsistent with both the huge financial burden faced by the PBM Defendants from the "catastrophic" over-spending and the typically low operating profit margins (5-6% range) for Part D plan sponsors in their annual bids submitted to CMS.

416. In reality, the massive "catastrophic" cost over-runs should have reeked financial havoc among PBM Defendants in Part D, but it never materialized.

417. To put the magnitude of this unforeseen plan sponsor cost-sharing burden in perspective, the Part D plan bids for all sponsors across the nation in 2007 included "expected profits" of only $1.07 billion. GAO Report OEI-02-08-00460, Medicare Part D Reconciliation Payments for 2006 and 2007, September 2009.

418. Based upon the 2015 plan bids (average $130/beneficiary) and annual enrollment (39.2 million people), we estimate aggregate Part D profits in the $3.0-3.5 billion range for aggregate US Part D plan sponsors for 2015.

419. There is no mathematical possibility that the dominant PBM Defendants could handle these massive unforeseen 2013-2015 “catastrophic” cost-sharing requirements (approximately $2.4 to $3.9 billion), without severe disruption to their financial performance and the overall Medicare Part D program.

420. This amount of unforeseen “catastrophic” cost-sharing would have negated virtually all Part D profits for the three year period.

421. The only way the PBM Defendants could avoid the tremendous dislocation from this unforeseen “cost sharing” exposure is through another secretive fraudulent financial arrangement with drug manufacturers.

422. We concluded that, in many instances, manufacturers are fraudulently excusing the PBM Defendants from their 15% “catastrophic” cost-sharing exposure (in their role as plan sponsors), in order to advance the now pervasive "service fee" pricing scheme.

423. We will Novartis’ Gleevec to illustrate the scale of potential plan sponsor “cost-sharing” fraud. See **Exhibit 13**.

424. The annual AWP cost/patient of Gleevec increased from about $38,572 in 2006 to the $147,788 in 2015, prior to its early 2016 US patent expiration. In 2015, Gleevec was the second

top-spending cancer drug in Part D (after only Celgene's Revlimid).

425. In Part D, in 2006, the plan sponsor would be responsible for 15% of all Gleevec costs above the $3,600 threshold, or about $5,246 in annual costs, payable to the manufacturer, Defendant Novartis.

426. After the massive price increases, the PBM Defendants (in their role as plan sponsor) would be responsible in 2015 for nearly $21,463 in "cost-sharing" for each Part D Gleevec-treated patient above the modest $4,700 threshold that year.

427. With these dynamics, it would appear mathematically impossible for the dominant PBM Defendants to pay the escalating plan sponsor Gleevec "cost-sharing" burden driven by the massive price increases.

428. The 15% plan sponsor "cost-sharing" burden would be nearly twice as much as the "service fees" received from a standard "8% of revenue" "specialty" drug contract, leading to considerable losses for the PBM Defendant.

429. With apparently minimal, if any, "rebates" for Gleevec and other oral cancer "specialty" drugs, Novartis "service fees" for Gleevec are the sole source of PBM Defendant profits related to the product.

430. Beyond Gleevec and the other Defendant CML drugs, we suspect widespread abuse of the Part D plan sponsor "catastrophic" cost-sharing requirements for a wide array of extreme-priced oral "specialty" cancer drugs.

431. Just a few of the numerous other fast-inflating oral cancer "specialty" drug candidates for severe "service fee" and "catastrophic" abuse include: Celgene's Revlimid (myeloma, Part D's top-spending cancer drug, AWP $225,000 patient/year), Johnson & Johnson's Imbruvica (leukemia, AWP $178,000 patient/year), Bayer's Nexavar (renal cell/liver cancer, AWP

$136,000 patient/year), Roche's Tarceva (lung cancer, AWP $123,000 patient/year) and Tesaro's Zejula/Clovis' Rubraca/Astra Zeneca's Lynparza (PARP inhibitors for ovarian cancer, AWP $215-300,000 patient/year).

Exhibit 13
Medicare Part D: "Catastrophic" Cost-Sharing Fraud
Novartis's Gleevec

	2006	2015	Change 2006-2015
AWP Cost/Patient/Year ($)	**$38,572**	**$147,788**	**$109,216**
Annual Part D Catastrophic Threshold ($)	$3,600	$4,700	
Drug Costs Above Catastrophic Threshold ($)	**$34,972**	**$143,088**	**$108,116**
PBM/Plan Sponsor Catastrophic Cost Sharing (%)	15%	15%	-
PBM/Plan Sponsor Catastrophic "Cost Sharing" ($)	**$5,246**	**$21,463**	**$16,217**
PBM "Service Fees"/Gleevec Patient ($ @ 8%)	**$3,086**	**$11,823**	**$8,737**

Source: Redbook/Truven, CMS, PhRMA.

432. If the Manufacturer Defendants are commonly "forgiving" the PBM Defendants from their Part D "catastrophic" exposure, these amounts should be properly reported as discounts via Direct and Indirect Remuneration ("DIR") reports to CMS, serving to lower program "negotiated" drug prices.

433. However, with Part D reimbursement based on AWP "list" prices, we expect discovery to uncover wide-ranging "cost-sharing" reporting and financial fraud for Gleevec and

other extreme-priced "specialty" oral cancer drugs.

434. These "forgiven" costs are another form of "kickbacks" and false claims required to advance the pervasive "service fee" pricing scheme.

435. Due to very limited public disclosure by either CMS or the Defendants, we have not attempted to estimate the magnitude of potential Part D plan sponsor "catastrophic" cost-sharing fraud.

436. However, in recent years, the Part D "cost-sharing" financial fraud likely exceeds that from direct "service fee" payments for many extreme-priced "specialty" drugs.

437. The underestimation of "catastrophic" spending in annual plan sponsor bids leads to artificially low Part D beneficiary premiums, which are beneficial to the both the PBM and Manufacturer Defendants.

438. Low Part D premiums are a key marketing tool for the PBM Defendants and have contributed to accelerating enrollment in recent years.

439. Both Defendant parties gain political capital from low Part D premiums. The Defendants, politicians and related parties frequently cite the low premium levels as indicative of Part D's success in controlling spending, while largely ignoring the exploding "catastrophic" Part D cost increases in recent years.

440. Of course, in a properly-functioning program, the Defendant strategy falls apart if the Part D plan sponsors were actually bearing their share of the vast "catastrophic" excess spending.

441. Key Part D regulatory shortfalls have contributed to fraudulent abuse of the Part D plan sponsor "cost-sharing" cost-control mechanism. If Part D plan sponsors were truly independent entities, "catastrophic" risk-sharing would force legitimate, aggressive price

negotiations with manufacturers by the PBM Defendants.

442. Second and surprising to us, Medicare Part D does not require separate reporting and accounting (in PDE or any other CMS submissions) of the plan sponsor 15% "catastrophic" cost-sharing requirement, despite it being the primary mechanism for controlling high-cost "specialty" drug spending.

443. These regulatory shortfalls regarding plan sponsor "catastrophic" cost-sharing shrouds this important issue in secrecy that requires full investigation in the public interest.

444. With "specialty" drugs now the primary driver of both the biopharmaceutical and PBM industries, the apparent failure of the plan sponsor "catastrophic" cost-sharing mechanism now threatens the long-term viability of the Part D program.

EVIDENCE OF THE "FEE" SCHEME – DIRECT INSIDER COMMENTARY

445. Dr. Borzilleri obtained confirmation of Defendant intentional participation in the fraudulent systemic "service fee" scheme from his attendance at a one-of-kind conference specifically focused on the topic. On October 7-8, 2013 in Philadelphia, PA, Dr. Borzilleri attended a two-day conference entitled, "Fair Market Value of Bona Fide Service Fees".

446. Consistent insider commentary over the two-day conference verified all key aspects of the fraudulent "service fee" arrangements between the Manufacturer and PBM Defendants.

447. The conference presenters and attendees were acutely aware that "service fee" contracts were routinely structured as a "percent of revenues", inclusive of massive price increases. Furthermore, manufacturers and PBMs continue to structure contracts in this manner despite clear legal FMV risks and repeated legal/consultant advice against the practice. Detailed commentary from the conference is provided in the next section.

448. In December 2014, Dr. Borzilleri obtained corroboration of the BFSF scheme

during a “one-on-one" meeting at an investor conference with James Schoeneck, the former CEO of Depomed, a mid-capitalization biopharmaceutical company. Depomed marketed Gralise for the treatment of neurologic pain, which competed directly with Defendant Pfizer’s Lyrica.

449. When asked about the competitive justification for coincident severe Gralise and Lyrica price increases, Mr. Schoeneck casually stated "well, PBMs don't make their money off of rebates anymore". He said, the "PBMs make their money off of service fees" and you just have to "play ball with them" to get a contract. He then stated that the typical contract required paying "3-4% of revenues", which would include the price increases".

450. Depomed had just recently announced the successful negotiation of contracts with the three-leading stand-alone PBMs at the time, Express Scripts, CVS Health and Catamaran for both private insurance and Part D formulary access for Gralise. Catamaran was acquired by Defendant UnitedHealth Group in 2015.

451. Both Pfizer’s Lyrica and Depomed’s Gralise are characterized as “traditional” pill drugs in PBM drug formularies, not high-cost “specialty” therapies. The “3-4% of sales” “service fee” contract rate (inclusive of price increases), quoted by Mr. Schoeneck, is consistent with the “traditional” drug rate disclosed by the PhRMA in its November 2017 report.

DETAILED COMMENTARY FROM “FMV OF BFSF INDUSTRY CONFERENCE”

452. Dr. Borzilleri obtained definitive confirmation of the “service fee” scheme from his attendance at an industry expert conference focused specifically on the topic. The two-day conference, sponsored by CBI, was entitled "Fair Market Value of Bona Fide Service Fees". The event was held in Philadelphia on October 7-8, 2013.

453. CBI describes itself as "the leading provider of market-driven, unbiased conferences for the pharmaceutical, biotechnology, medical device and healthcare industries."

454. The conference was attended by senior corporate government program staff from the biopharmaceutical and drug distribution industries, as well as representatives from leading consulting and law firms that advise industry regarding BFSFs and FMV. Of particular note was the absence of CMS or any other government agencies at the conference.

455. Key staff from the Defendants were in attendance, including Amgen, AbbVie, Bristol-Myers Squibb, Pfizer, Sanofi and Express Scripts. Also present were representatives from other leading drug manufacturers and service providers, including Johnson and Johnson, Glaxo, Astellas, Gilead, Mylan, Otsuka and Diplomat Specialty Pharmacy.

456. The legal and consulting firms, which gave most of the presentations and led discussions, are the leading firms among a narrow group of pharmaceutical and PBM industry advisors with dedicated BFSF and FMV healthcare practices. As per their corporate websites, these firms advise the majority of top pharmaceutical and biotechnology companies regarding compliance with government regulations.

457. Besides CIS, consultant firm presenters included representatives from Huron Consulting and Navigant Consulting.

458. On the legal front, presenters included representatives from King & Spalding, Reed Smith, Hogan Lovells and Sidley Austin. See **Exhibit 14** for a list of conference presenters and attendees.

Exhibit 14

"First Ever" Fair Market Value of Bona Fide Service Fees Conference

October 7-8, 2013, Philadelphia, PA

Presenter/Attendee List

Name	Title
Presenters (in chronological order)	
Tom Evegan	Senior Director, Commercial Contracting at Compliance Implementation Systems (CIS)
John Shakow	Partner, King & Spalding
Mark Linver [1]	Managing Director, Huron Consulting Group
Stephanie Gilson	Assistant General Counsel, Johnson & Johnson
Christopher Jackson	Corporate Attorney, Otsuka American Pharmaceuticals, Inc.
Donna White	Senior Director, Contracts and Compliance at Cornerstone Therapeutics
Joseph Metro	Partner, Reed Smith LLP
Mark Dewyngaert, Ph.D.	Managing Director, Huron Consulting Group
Michael Hepburn[2]	Senior Director, Government Contract Compliance at Janssen Pharmaceuticals, Inc.
Doris Chern[2]	Senior Manager, Pricing Strategy and FMV at Janssen Pharmaceuticals, Inc.
Jim Abrams	Director, Government Pricing and Reporting at Mylan Pharmaceuticals
Trevor L. Wear	Senior Associate, Sidley Austin, LLP
Julie DeLong, CFA	Director, Valuation and Financial Risk Management at Navigant Consulting, Inc.
Isabel P. Dunst	Partner, Hogan Lovells US LLP
John Moose, MBA, CPA, ABV	Project Leader, Huron Consulting Group
Other Attendees	
Sajid Saeed	Director Fee-for-Service, Glaxo Smithkline
Greg Haverkamp	Senior Manager of Government Contracts and Compliance, Novo Nordisk
Mitzi Cole	Strategic Pharmaceutical/Biotechnology Legal Counsel, Pfizer
Cynthia Bass	Associate General Counsel, Sanofi US
Cheryl Allen	VP Development/Industry Relations, Diplomat Specialty Pharmacy
Allyson Behm	Senior Corporate Attorney - Regulatory, Astellas

Jason Carter	Senior Manager, Government Analytics & Compliance, Roche/Genentech
Josh Parker	Director, Product Marketing, Express Scripts/Accredo Health
Lyndsay Nahf	Director, Central Consultancy Group, AbbVie
Linda Ozark	STAR Project Manager, Marketing Operations Systems, AbbVie
Jill Thompson	Senior Counsel and Assistant Secretary, NPSP Pharmaceuticals
John Walsh	Director Trade Account Management, Pfizer
Christine Morse	Senior Attorney, Novo Nordisk
Jamie Rowe	Senior Category Manager, Amgen

[1] Mark Linver did not attend the conference; his presentation was given by his colleague, Mark Dewyngaert

[2] Janssen Pharmaceuticals is a division of Johnson & Johnson

Source: CBI conference agenda and attendee poster from conference, Corporate websites.

459. At the conference, Dr. Borzilleri directly heard extensive commentary from the "insider" conference presenters, which fully corroborated the "service fee" allegations outlined in this Complaint. Dr. Borzilleri noted considerable trepidation among the presenters and audience regarding legal exposure throughout the two-day conference.

460. All key components of the fraud were verified via presentations, candid discussions and direct quotes at the conference, namely:

a. "Service fees", rather than manufacturer rebates/discounts, have become the primary vehicle for manufacturer compensation of PBMs/specialty pharmacies;

b. The standard contract terms between manufacturers and service vendors utilize "percent of revenue" terms; without adjustment even for severe price increases, despite broad awareness of FMV fraud risk.

c. The experts recognize that the majority of "service fees" should legitimately be valued via the straightforward "Cost Approach" to FMV assessment, but it is rarely

being done;

d. The large service vendors, including the PBMs, are using their considerable negotiating leverage to preserve “percent of revenue” service contracts with manufacturers.

461. In the first few minutes of his opening statements, Tom Evegan of CIS, the Chairman of the conference, stated that "fees were the key to government pricing" and the majority of compensation to service providers from manufacturers had "shifted from rebates to fees".

462. On the second day, Mr. Dewyngaert, a senior consultant from Huron Consulting, stated that "service fee agreements" accounted for a "substantial pool of money" and were the "main source of income" for service vendors.

463. A key presenter was John Shakow, from the law firm King & Spalding. Mr. Shakow disclosed that he was a defense lawyer in the Streck Qui Tam case, which included allegations of “service fee” abuse in the Medicaid program.

464. After providing background on the history of BFSFs and potential legal risks, Mr. Shakow stated that he was "not a fan” of “percent of revenue” contracts and that manufacturers need to "consider whether percent of sales can be consistent with FMV as prices rise". He stated it was "a lot easier to have a fixed fee per unit of service", which would make him "less worried regarding the impact of price increases".

465. Mr. Shakow went on to say that “percent of revenue” arrangements "may bear no relation to the value of service unless (the service is) price-based". He expected that "percent of revenue" deals will be "challenged in the future".

466. Mr. Shakow emphasized that the manufacturer’s handling of fees must be able to "withstand review/auditing by an independent party, which can determine the same FMV", as well

as "justify the FMV to an outside party brought in by the government". He stated that the government will "look beyond the agreement and evaluate the true nature of the fees, via emails, communications, interviews and sworn testimony", in its search for “intent".

467. In their joint presentation, Isabel P. Dunst, a partner at Hogan Lovells and Julie DeLong, the Director of Valuation and Financial Risk Management at Navigant Consulting, offered somewhat contrasting viewpoints regarding valuation methodologies. Ms. Dunst stated that she "did not recommend percent of sales" contracts to her manufacturer clients, while Ms. DeLong indicated more flexibility.

468. Ms. DeLong stated that she "can value anything" and was comfortable "translating per unit fees to percentage of revenue". Ms. DeLong elaborated, stating that "some want to be paid in different ways" and that she could "translate FMV into a dollar amount per month or year, as well as a percent of revenues". During this discussion, Ms. Dunst stated that she hoped "the conference was not being recorded".

469. Ms. DeLong further stated that the FMV was a "snapshot in time" and "percent of revenue" deals had greater risk when linked to fast-rising “list” prices.

470. An audience member then asked about the proper FMV handling of fees for a $100 versus a $1,000 prescription with the same number of pills. Ms. Dunst, of Hogan and Lovells, replied that a "real problem was developing with percent of revenue" contracts. We view this commentary as particularly relevant for fast-inflating, extreme-priced oral “specialty” drugs, which may not require significant legitimate support services.

471. Numerous presenters stated the "Cost Approach" is the most legally-justifiable FMV methodology for the vast majority of services provided for manufacturers by service vendors. In the “Cost Approach”, the payment is determined by a straightforward determination

based upon the staffing, time and resources required to provide a specific service.

472. In his discussion of contracting processes, John Moose of Huron Consulting stated that the negotiating parties must recognize that "most of the value of services comes from the connection with the patient" and that a "dollar amount per activity is the easiest to justify".

473. Julie DeLong and Isabel P. Dunst specifically discussed the topic of FMV for services provided for “specialty” drugs. Ms. Dunst stated that she "does not view the specialty channel any differently from other channels" regarding the handling of fees and FMV.

474. If a particular “specialty” service is "core" to the business model of the specialty pharmacy and "they are already doing it", the manufacturer "should not be paying for it". Ms. Dunst and Ms. DeLong indicated that virtually all the specialty pharmacy services are patient/unit based and should be valued using the "Cost Approach".

475. Despite the uniform recommendation of the "Cost Approach" for FMV “fee” determinations, conference presenters repeatedly admitted that this methodology is rarely used in practice. Rather, “percent of revenue” contracts, inclusive of all price increases, remain the industry standard.

476. A definitive moment in the two-day conference came during the final presentation of the first day given by Jim Abrams, the former Director of Government Pricing and Reporting at Mylan Pharmaceuticals. Mylan’s leading brand drug, Epipen (epinephrine for severe allergic reactions) has been a controversial product, with its vast US sales growth over the past decade driven by massive price increases.

477. Mr. Abrams took a simple poll of the audience. He asked attendees to raise their hands "if they were using a rigorous cost-plus approach to qualify fees" - only one person, among the 50-60 conference attendees, raised his hand.

478. John Moose of Huron Consulting specifically discussed the need for contract adjustments for rising drug prices. He stated that unless manufacturers put "adjustments in contracts for price changes", they "run the risk of paying too much". He stated that manufacturers need to "refresh" contracts for price increases and service changes, in order to maintain reasonable FMV determinations. Despite his expert recommendation, Mr. Moose then admitted that "he had not done any refreshes for service contracts".

479. In her presentation, Stephanie Gilson, the Chief Counsel at Johnson & Johnson, admitted that "percent of WAC (Wholesale Acquisition Cost), deals are often not updated by manufacturers".

480. The considerable negotiating leverage of large service vendors, especially the PBM Defendants, pertaining to “service fee” contracts was apparent at the conference.

481. Jim Abrams of Mylan polled the audience of largely manufacturers and consulting/legal advisors, asking for an indication of who had "engaged vendors to assess fee structure". Out of the 50-60 attendees, only 2 raised their hands.

482. Tom Evegan of CIS then commented that "very few vendors were willing to provide the data" and were "worried" about doing so. Mr. Evegan expressed concern since "manufacturers were looking for documentation since manufacturers were responsible if ever challenged".

483. Mr. Shakow further stated that "up to a few years ago few contracts gave specifics regarding fees" and this "could be trouble".

484. Numerous expert presenters emphasized the need for manufacturers to insist on broad "audit rights" in their contracts with large service vendors, while admitting little success with these requests.

485. Mr. Shakow stated that shifting away from "percent of revenue" service contracts was difficult for manufacturers because vendors "all want percent of revenue deals" and change required "getting partners to agree".

486. Mark Dewyngaert from Huron stated that "often partners (i.e. service vendors) will not allow cost plus" fee determinations.

487. Ms. Gilson stated Johnson & Johnson was "trying to work with intermediaries" in order to decrease their reliance on "percent of WAC" contracts, but were getting "strong pushback from service providers". She stated that to change these business practices may require either a "manufacturer industry initiative" or a "CMS mandate".

488. Finally, expert commentary indicated that the federal government has been struggling to address industry “service fee” practices. Ms. Gilson stated that the Office of the Inspector General (OIG) "has been looking at these practices", but really had little knowledge" and the "learning curve takes time". She further stated that the OIG auditors had only just "engaged" with J&J directly on this issue recently in the "second quarter of 2013".

489. An attendee agreed that the OIG was "behind industry" and asked Ms. Gilson when the government would be "dangerous enough to understand how industry works". Ms. Gilson responded that she thought "CMS was getting burned out because a lot of stakeholders were in their ear".

DEFENDANT PRODUCT/THERAPEUTIC CATEGORY REVIEW

A. Anti-Tumor Necrosis Factor (TNF) Category:

490. Self-injected anti-TNF specialty drugs are leading biologic therapies for several major inflammatory conditions, including rheumatoid arthritis (the largest market), Crohn's

disease, ulcerative colitis and psoriatic arthritis.

491. In the US, the anti-TNF market has long been dominated by two long-available products, Amgen's Enbrel (enterecept, FDA approval 1997) and AbbVie's Humira (adalimumab, FDA approval 2003). Both Enbrel and Humira act by blocking tumor necrosis factor (TNF), a cytokine that plays a key role in inflammatory processes and resulting joint damage.

492. Over the past decade, Humira has steadily been taking market share from Enbrel, primarily due to a modestly improved dosing schedule (a biweekly injection versus weekly for Enbrel) and a greater number of medical indications. Humira is approved for Crohn's disease and ulcerative colitis in the US, while Enbrel is not.

493. In recent years, two additional anti-TNF therapies, UCB Group's Cimzia (certolizumab, FDA approval 2008) and Johnson & Johnson's Simponi (golimumab, FDA approval 2009) have become available. Both of these new products offer clinical profiles similar to Enbrel and Humira, with dosing advantages over both of the older anti-TNF agents. The maintenance doses for both Cimzia and Simponi are given monthly.

494. An intravenous anti-TNF therapy, Remicade (infliximab, Johnson & Johnson, FDA approval 1998) is marketed in the US for the treatment of rheumatoid arthritis, Crohn's disease, ulcerative colitis, psoriasis and psoriatic arthritis. Remicade is not implicated in this case because it is reimbursed via Medicare Part B, not Part D.

495. In 2009, Johnson & Johnson also received approval for an infused version of Simponi, called Simponi Aria. This formulation is similarly reimbursed via Medicare Part B and not implicated in this case.

496. The FDA-approved prescribing information for these subcutaneous four anti-TNF therapies indicate very similar clinical profiles. All four provide very similar clinical benefits in

rheumatoid arthritis, as measured by standard American College of Rheumatology (ACR) criteria. The side effect profiles of the drugs are nearly identical, and all carry a "Black Box" safety warning from the FDA regarding the risk of rare severe infections and malignancies.

497. Medical experts consider the clinical profiles of these four subcutaneous anti-TNF therapies to be clinically-interchangeable. In fact, leading US medical organizations do not discern between the products in their clinical guidelines.

498. In its 2012 updated guidelines for the treatment of rheumatoid arthritis, the American College of Rheumatology states: "If a patient has moderate or high disease activity after three months of methotrexate monotherapy or DMARD combination therapy….the panel recommends adding or switching to an anti-TNF biologic, abatacept or rituximab." 2012 Update of the 2008 American College of Rheumatology Recommendations for Disease-Modifying Antirheumatic Drugs and Biologic Agents I the Treatment of Rheumatoid Arthritis, Arthritis Care & Research, Vol. 64, No. 5, May 2012, pp. 625-639.

499. The major US medical organization clinical guidelines for Crohn's disease also do not separate the three anti-TNF therapies that are approved for use. According to the American Gastroenterological Association Crohn's disease guidelines: "We recommend using anti-TNF-alpha drugs to induce remission in patients with moderately severe Crohn's disease who have not responded to standard therapies. As a group, the three anti-TNF-alpha drugs that are FDA-approved for the treatment of Crohn's disease (infliximab, adalimumab and certilizumab) are more likely than placebo to induce remission in patients with moderately severe Crohn's disease refractory to standard therapies." The AGA Institute Clinical Practice and Quality Management Committee, March 04, 2014.

500. These four anti-TNF drugs also compete for US patients with an increasing number

of non-TNF rheumatology drugs, with similar efficacy, that have been approved over the past decade, including Orencia (abatacept, Bristol-Myers, FDA approval 2005), Stelara (ustekimumab, Johnson & Johnson, 2009), Actrema (tocilizumab, Roche, 2010), Xeljanz (tofacitinib, Pfizer, 2012), Ilaris (canakinumab, Roche, 2013), Otezla (apremilast, Celgene, 2014) and Olumiant (Eli Lilly, baricitinib, 2018).

501. The availability of four clinically-similar subcutaneous anti-TNF drugs, as well numerous other new clinically-similar therapeutic options, provides the dominant PBM Defendants considerable negotiating leverage with manufacturer on behalf of taxpayers and beneficiaries in the Medicare Part D program.

502. Furthermore, the motivation for PBMs (to seek rebates/discounts and to prevent price increases) should be high since the anti-TNF category is among the top-spending drug categories for all insurance plans in the nation. AbbVie's Humira is the top-selling drug in the US and Enbrel is among the top-five spending drugs in many insurance plans.

503. However, contrary to normal competitive dynamics, vast and uniform price inflation has occurred among the anti-TNF and other rheumatology drugs. As in the US multiple sclerosis category, new therapies are standardly launched at nearly the same price as fast-inflating older products, with ongoing aggressive increases for all products.

504. The pricing trends are most incongruous for Amgen's Enbrel, for which severe price increases have occurred despite eroding use by physicians and patients. Based on IMS prescription trends, Amgen's disclosures and our estimates, the number of US patients treated with Enbrel has decreased by about 20% between 2006 and 2017.

505. Despite its eroding use and market share, the annual AWP annual cost/patient of Enbrel has increased four-fold, from about $17,629 in 2005 to about $70,343 in mid-2018. See

Exhibit 15.

Exhibit 15
US Anti-TNF Therapies
AWP Annual Patient Costs ($)

	Humira	Enbrel	Cimzia	Simponi
Company/US Launch	**AbbVie (2003)**	**Amgen (1997)**	**UCB (2008)**	**J & J (2009)**
2005	**$17,277**	**$17,629**	-	-
2006	20,920	18,493	-	-
2007	19,011	19,399	-	-
2008	20,920	21,347	**$19,874**	-
2009	21,945	22,820	21,062	**$23,791**
2010	24,149	25,111	22,978	24,933
2011	25,815	26,592	25,309	27,960
2012	29,500	30,389	30,301	31,951
2013	36,038	34,728	36,284	36,513
2014	41,956	42,820	39,876	42,896
2015	49,425	53,825	43,823	50,103
2016	58,222	59,154	50,353	54,562
2017	63,113	64,123	55,187	59,418
2018	**$69,235**	**$70,343**	**$57,836**	**$64,706**

Source: Redbook/Truven.

506. Amgen has reported large increases in US Enbrel sales over the past decade, entirely driven by frequent, large price increases. Reported US Enbrel sales have increased from $2.47 billion in 2005 to $5.2 billion in 2017. Without price increases, US Enbrel sale would be in the $1.9 billion range in 2017. All of Enbrel's cumulative US sales gains of $19.1 billion over the

past decade are caused by the fraudulent "service fee" scheme, with an estimated 30% attributable to Medicare Part D.

507. As a newer drug with modest advantages over Enbrel, volume growth for AbbVie's Humira has been far stronger. US Humira sales have increased from $560 million in 2005 to $12.4 billion in 2017, with about two-thirds of the growth due to severe price increases. As such, the majority of Humira's astounding cumulative US revenue gains of $32.3 billion over the period are attributable to the scheme.

508. Indicative of anticompetitive activity, despite an intense battle for US market share, the cost of both Enbrel and Humira has increased in virtual lockstep (with large price increases often within days of each other) over the past decade. Furthermore, the pace of the price increases has accelerated in recent years, with both up 100% in unison just since the start of 2013.

509. Consistent with the "service fee" scheme, the combined market share for the newer anti-TNF drugs, Simponi and Cimzia, remains quite modest (in the 10% range) despite the widening AWP cost spread with Humira and Enbrel in recent years. See **Exhibit 15**.

510. In the scheme, both the manufacturers and PBMs are incented to preserve the vast profits stream from the market-leading "blockbusters", Humira and Enbrel, rather than seek larger rebates and lower drug costs for their payer clients from newer competitors.

B. <u>Chronic Myeloid Leukemia (CML) Category:</u>

511. Chronic Myeloid Leukemia (CML) is a form of leukemia characterized by the increased and unregulated growth of predominantly myeloid (white blood) cells. CML is caused by the translocation of a specific gene (ABL) from one chromosome (9) to another (22). In the United States, the average age of diagnosis is 60-65 years old, with approximately 4,600 new cases per year.

512. Over the past 15 years, the long-term survival of CML patients has markedly improved with the arrival of breakthrough targeted oral therapies, called Tyrosine Kinase Inhibitors (TKIs). The first TKI drug, Novartis' Gleevec (imatinib), quickly gained wide use following its US approval in 2001.

513. Two additional major TKIs have been approved for the treatment of CML over the past decade, namely Bristol-Myer's Squibb's Sprycel (dasatinib, US approval 2006) and Novartis' follow-up therapy, Tasigna (nilotinib, US approval 2007).

514. In more recent years, two additional niche TKI CML therapies have been approved in the US, Pfizer's Bolsulif (bosutinib) and Ariad's Iclusig (ponatinib). The use of these latter two agents is primarily restricted to the smaller refractory CML population.

515. Both Sprycel and Tasigna were initially approved for the treatment of CML patients refractory to Gleevec therapy, but gained expanded labelling for newly-diagnosed CML patients in 2010. According to their FDA-approved labels, both Sprycel and Tasigna have demonstrated superior clinical responses in short-term head-to-head trials vs. Gleevec.

516. According to the leading US CML medical organization, the Leukemia and Lymphoma Society (LLS), "Findings from studies of each drug (Sprycel and Tasigna) show faster complete cytogenic response (CCyR) and molecular response (MR) than the response with Gleevec. These drugs may prove to be associated with better long-term outcomes." Leukemia and Lymphoma Society Chronic Myeloid Leukemia Information Booklet, Revised 2014, www.LLS.org.

517. However, the LLS document further states: "neither Sprycel nor Tasigna has been shown to result in longer survival" (than Gleevec). Pending long-term comparative survival data, all three TKIs remain viable first-line CML therapies.

518. The LLS also indicates that the tolerability of both Sprycel and Tasigna compares favorably to Gleevec. "In a one-to-one comparison with Gleevec, most side effects were reported less commonly in patients treated with Sprycel". Similarly, "In a one-to-one comparison with Gleevec, most side effects were reported less commonly in patients treated with Tasigna". Leukemia and Lymphoma Society Chronic Myeloid Leukemia Information Booklet, Revised 2014, www.LLS.org.

519. Both Sprycel and Tasigna have steadily gained market share from Gleevec over the past decade. Gleevec's US total prescription share among these three leading CML drugs declined from 100% at the start of Part D to 85% at year-end 2010 and 65% at year-end 2014. The market shares for Sprycel and Tasigna reached 9% and 6%, respectively, in 2010 and 17% and 16%, respectively, in 2014.

520. Due to the competition from these two new TKI drugs, the clinical use of Gleevec has moderated considerably over the past decade. Based upon IMS data and our estimates, the number of US patients treated with Gleevec increased by about 20% between 2005 and 2015. However, between 2010 and 2015 (just prior to its February 2016 US patent expiration), US Gleevec-treated patients declined by about -6%.

521. In a properly-functioning US market, these competitive factors would be expected to limit price inflation for Gleevec and the other TKI drugs.

522. Furthermore, with the majority of CML patients in Medicare Part D (about 60%), the PBM Defendants, in their role as plan sponsors, should be highly-incented to negotiate aggressively with Novartis in order to limit their escalating "catastrophic" cost-sharing exposure as prices rise.

523. Despite these competitive factors, Novartis and Bristol-Myers Squibb have

benefited from staggering price increases for the their TKI drugs. The AWP cost/patient/year for Gleevec has increased from about $36,000 in 2005 to nearly $150,000 in 2015.

524. Furthermore, the magnitude of Novartis's Gleevec price increases counterintuitively accelerated starting in 2010, as the volume started to decline. See **Exhibit 16**.

Exhibit 16
US Chronic Myeloid Leukemia (CML) Therapies
AWP Annual Patient Cost ($)

Company/US Launch	Gleevec Novartis (2001)	Sprycel Bristol-Myers (2006)	Tasigna Novartis (2007)
2005	**$35,734**	-	-
2006	38,572	**$64,496**	-
2007	41,619	76,739	**$83,238**
2008	48,050	80,006	$91,395
2009	55,395	92,411	105,420
2010	66,991	111,613	115,856
2011	77,305	115,074	119,448
2012	93,368	125,299	125,300
2013	101,772	129,058	129,686
2014	122,361	140,662	142,707
2015	147,788	151,211	151,269
2016	147,788	164,966	164,942
2017	147,788	176,348	180,941
2018	**$147,788**	**$188,516**	**$198,854**

Source: Redbook/Truven.

525. Despite an intense battle for patients in a mature market, the AWP prices of Sprycel and Tasigna have vastly increased since their launch a decade ago.

526. Price inflation for Sprycel and Tasigna has continued in recent years despite wide availability and greater use of generic Gleevec. The AWP cost of Sprycel has increased from about

$65,000/patient/year at launch in 2006 to $150,000 in late 2015. The cost has increased another 25% to nearly $190,000 patient/year in mid-2018.

527. Ongoing inflation has been even greater for Novartis' Tasigna. Its AWP price has increased another 30% since 2015, with an annual patient cost in the $200,000 range in mid-2018.

528. Based upon its SEC-reported financial statements, Novartis has received large financial gains from these severe price increases.

529. Novartis reported an increase in US Gleevec sales from $524 million in 2005 to $2.5 billion in 2015. Without price increases, US Gleevec sales would have only been in the $700 million range for 2015.

530. The cumulative financial impact of these anticompetitive Gleevec price increases on the Part D program and the private insurance market over the past decade is about $7.4 billion. The vast majority of these Gleevec financial gains by Novartis have been driven by the fraudulent "service fee" scheme. We estimate that 60% of this fraud has been in Medicare Part D.

531. Novartis's reported US sales of Tasigna have increased from $30 million in 2008 to $810 million in 2017. We estimate that about 40% of this growth is attributable to vast price increases enabled by the scheme.

532. Without price increases, US Tasigna sales would have only been in the $480 range in 2017. We estimate a cumulative fraudulent impact for Tasigna since launch at $1.0 billion, with 60% attributable to Medicare Part D.

533. Bristol-Myers Squibb's' reported US sales of Sprycel have increased from $22 million in 2006 to $1.1 billion in 2017. We estimate that about 60% of this growth is attributable to vast price increases enabled by the scheme.

534. Without price increases, US Sprycel sales would have only been in the $460 range

in 2017. We estimate a cumulative fraudulent impact for Sprycel since launch at $2.5 billion, with 60% attributable to Medicare Part D.

C. Diabetes Insulin Category:

535. The US diabetes therapeutic category includes four major brand categories; two oral segments and two injectable segments. The two major oral segments are DPP-4 inhibitors and SGLT-2 inhibitors. The two major injectable segments are GLP-1 agonists and insulins. Following an array of recent new product approvals, all four of these segments now have a wide array of clinically-interchangeable drugs that should afford considerable PBM Defendant negotiating leverage and cost-savings potential.

536. The insulin category is divided into short-acting and long-acting products. Short-acting products are typically used around meals, while long-acting versions provide baseline insulin levels throughout the day.

537. Within the short-acting sub-segment, newer insulin analogues (Eli Lilly's Humalog, Novo Nordisk's Novolog and Sanofi's Apidra) offer faster onset that long-marketed regular insulins, such as Eli Lilly's Humulin and Novo Nordisk's Novolin.

538. The dominant long-acting insulin product has been Sanofi's Lantus, with competition from Novo Nordisk's similar product, Levemir.

539. All insulins are administered as subcutaneous injections and require individualized patient dosing depending upon numerous factors, including age, weight, diet, and insulin sensitivity/resistance.

540. As with the other diabetes brand segments, severe and uniform AWP price inflation of virtually all insulin therapies suggests broad-based “service fee” fraud tied to price increases.

541. Despite complete clinical interchangeability, the average AWP cost/patient/year for

Eli Lilly's and Novo Nordisk's long-marketed Humulin (FDA approval 1982) and Novolin (FDA approval 1991), respectively, has increased approximately 5-fold since the start of Part D.

542. Based upon an estimated average daily dose of 50 units, the average AWP annual cost of therapy for Humulin and Novolin has increased in lock-step from the $605-630 range in 2005 to $3,000-3,250 range in mid-2018. See **Exhibit 17**. Many diabetic patients require far more that a 50 unit daily dose due to insulin resistance and/or greater body weight.

Exhibit 17
US Short-Acting Insulin Therapies
AWP Annual Cost of Therapy ($)
Based upon 50 unit daily dose

	Humulin R	Novolin R
Company/US launch	**Eli Lilly (1982)**	**Novo Nordisk (1991)**
2003	**$534**	**$557**
2004	561	585
2005	606	631
2006	660	660
2007	723	723
2008	840	818
2009	890	899
2010	1,058	1,187
2011	1,428	1,436
2012	1,664	1,660
2013	1,989	1,985
2014	2,402	2,399
2015	2,810	2,794
2016	3,020	3,016
2017	3,257	3,016
2018	**$3,257**	**$3,016**

Source: Redbook/Truven.

543. In the long-acting segment, based on an average daily dose of 50 units, the annual

AWP cost/patient/year of both Sanofi's Lantus (FDA approval 2001) and Novo Nordisk's Levemir (FDA approval 2005) has increased nearly four-fold in lockstep from the $1,400-1,500 range in 2006 to the $5,900-6,100 range in mid-2018. See **Exhibit 18**. As with the short-acting insulins, many diabetics require far more than a 50 unit daily dose, due to insulin resistance and/or greater body weight.

Exhibit 18
US Long-Acting Insulin Therapies
AWP Annual Cost of Therapy ($)
Based upon 50 unit daily dose

	Lantus	Levemir
Company/Year Launch	**Sanofi (2000)**	**Novo Nordisk (2005)**
2003	**$978**	-
2004	1,162	-
2005	1,318	-
2006	1,405	**$1,528**
2007	1,545	1,582
2008	1,776	1,776
2009	1,883	1,883
2010	2,176	2,206
2011	2,500	2,492
2012	2,886	2,959
2013	4,189	4,189
2014	5,442	5,442
2015	5,442	5,891
2016	5,442	5,891
2017	5,606	5,891
2018	**$5,903**	**$6,127**

Source: Redbook/Truven.

544. While "service fee" fraud in the insulin market is widespread, this case targets two products in which Manufacturer Defendant SEC-reported US product revenues are most disparate

from underlying patient utilization trends; namely Sanofi's Lantus and Eli Lilly's Humulin. For these two products, the Manufacturer Defendants have garnered the majority of the illicit gains from the collusive price increases.

545. Over the past decade, driven primarily by repeated large price increases, Sanofi's Lantus grew to be the largest spending "non-specialty" and diabetes drug in both the private insurance market and Part D. Sanofi reported US Lantus sales of approximately $850 million in 2005 rising to about $5.8 billion in 2014, with about two-thirds of this growth due to price increases.

546. Without the massive price increases, 2014 US Lantus sales would have been in the $2.2 billion range. The US sales of Lantus have decreased since 2014 due to the launch of a brand generic version, Eli Lilly's Basaglar, and category price moderation due to increased public/political scrutiny of the diabetes market.

547. Overall, we estimate that the scheme has resulted in unwarranted Lantus costs in excess of $21.4 billion between 2006 and 2017, with an estimated 30% attributable to the Part D program.

548. The signs of pricing fraud with Eli Lilly's Humulin has been even more severe, although the absolute financial harm has been less, due to its smaller diabetes market share compared to Lantus.

549. Despite an estimated -60% decrease in the number of US treated patients, according to IMS data and corporate reports, Eli Lilly has reported an increase in annual Humulin US sales from $411 million in 2005 to $885 million in 2017.

550. Without the massive price increases, 2017 US Humulin sales would have been only in the $175 million range. Over the past decade, we estimate cumulative US Humulin pricing fraud

of $4.1 billion, with 30% attributable to Part D.

D. Defendant Pfizer Products:

551. In addition to the above three major therapeutic categories, we have also ascertained significant "service fee" pricing fraud for an array of Pfizer's major US brand drug products.

552. The Pfizer products targeted in this Complaint are Lyrica, Viagra, Celebrex, Chantix, Premarin, Pristiq and Relpax. Except for Lyrica, the US prescription volume for all these products has eroded considerably in recent years.

553. However, counter to sluggish and/or falling prescription volume, Pfizer has reported strong US sales for all these brand products over the past decade, driven by massive price increases. In aggregate, these seven products accounted for $6.8 billion of Pfizer's 2017 US revenues, representing about 40% of US brand drug sales and 25% of overall US sales.

554. Pfizer has instituted twice yearly price increases in the 10% or more range for each of these products for each of the past five years. The majority of this price inflation and related US sales has been enabled by fraudulent "service fee" arrangements between Pfizer and the PBM Defendants.

555. As noted previously, we received direct confirmation of the scheme from the CEO of a smaller specialty pharmaceutical company, Depomed, Inc., which competed directly with Pfizer's Lyrica in the neuropathic pain market.

556. Of note, all these targeted Pfizer drugs are "traditional" oral therapies, not "specialty" drugs. As "traditional" oral drugs, legitimate PBM Defendant "services" (beyond filling/shipping) are minimal for each of these products.

557. Pfizer's Lyrica (pregabalin) received FDA approval for three indications in September 2004; namely neuropathic pain associated with diabetic peripheral neuropathy (DPN),

postherpetic neuralgia (PHN) and as adjunctive therapy in the treatment of partial seizures in adults. Lyrica later received approval for treating fibromyalgia in June 2007.

558. Lyrica is structurally-related to gabapentin, a widely-used generic drug; both drugs share a similar mechanism of action. Lyrica offers a modest improvement in dosing (2-3 times a day vs. 3-4 times a day for gabapentin) and a greater number of approved indications.

559. Within the medical community, many physicians consider Lyrica to offer relatively minor clinical advantages compared to generic gabapentin, especially considering the extreme cost differential. The availability of other therapies for neurologic pain has also negatively impacted Lyrica's clinical use.

560. With these market dynamics, US prescription trends for Lyrica have been sluggish in recent years. According to IMS, total prescriptions growth for Lyrica has increase an average of 1-2% in recent years, with the overall number of US patients treated up by about 8% between 2010 and 2016.

561. Despite sluggish use and strong competition, the AWP price for a 150mg pill of Lyrica has increased 4-to-5 fold from $2.00 in 2006 to $8.92 in mid-2018. See **Exhibit 19**.

562. Driven by these frequent severe price increases, Pfizer has reported robust US Lyrica sales growth, with SEC-reported US sales rising from $717 million in 2006 to $3.46 billion in 2017. Lyrica is Pfizer’s top-selling US brand drug.

563. Without the massive price increases, Pfizer’s 2017 US Lyrica sales would only be in the $1.2 billion range, less than one-third of the reported number.

564. Overall, we estimate cumulative fraudulent US Lyrica sales of approximately $9.9 billion between 2006 and 2017. We estimate that 30% of the fraud has occurred in Medicare Part D.

565. Pfizer's Viagra (sildenafil) was FDA-approved for the treatment of erectile dysfunction in 1998. Viagra is a phosphodiesterase-5 (PDE-5) inhibitor. In 2003, two additional PDE-5 drugs, Eli Lilly's Cialis (tadalafil) and Bayer's Levitra were launched in the US. More recently, a fourth PDE-5 drug, Endo Pharmaceutical's Stendra (avanafil) was approved by the FDA in 2012. Intense competition in this mature and crowded therapeutic category has negatively impacted the usage of both Viagra and Cialis.

Exhibit 19
Pfizer Products
AWP Price and US Prescription Trends

Product	2006	2009	2012	2015	2018	Price Change 2006-2017	Change Prescriptions 2010-2016
AWP Price/Pill ($)							
Lyrica	**$2.08**	$2.83	$4.04	$6.94	**$8.92**	**4.3x**	**8%**
Viagra	**11.46**	17.49	26.72	45.45	**80.82**	**7.1x**	**-42%**
Celebrex	**3.34**	4.22	5.74	10.09	**14.47**	**4.3x**	**-20%**
Chantix	**1.92**	2.35	3.69	5.76	**8.60**	**4.5x**	**-14%**
Premarin	**1.40**	1.85	2.85	4.35	**6.43**	**4.6x**	**-57%**
Pristiq	**-**	4.29	5.90	10.14	**13.95**	**3.4x**	**-29%**
Relpax	**18.32**	23.82	33.92	45.45	**74.73**	**4.1x**	**-18%**

Source Redbook/Truven and IMS.

566. According to IMS, the annual US prescription volume for Pfizer's Viagra has declined about -42% between 2010 and 2016.

567. Despite sharply eroding use, the AWP price of Viagra increased seven-fold from $11.46, per 100 mg tablet, in early 2006 to $80.82 in mid-2018. See **Exhibit 19**. Of note, indicative of anticompetitive activity, the vast price increases have been similar and in lockstep for the other

three marketed PDE-5 drugs.

568. Driven by these severe price increases, Pfizer's SEC-reported US Viagra sales increased from $796 million in 2006 to $1.15 billion in 2016. The US sales of Viagra are now in decline, following its December 2017 US patent expiration. Without the price increases, US Viagra sales would have only been in the $300 million range in 2016.

569. All of Viagra's price-driven US sales growth has been enabled by fraudulent "service fee" arrangements with the PBM Defendants. Overall, we estimate cumulative Viagra fraudulent US sales of about $5.7 billion between 2010 and 2017. We estimate that 20% of this fraud has occurred in Medicare Part D.

570. While not targeted in this Complaint, we also suspect severe "service fee" pricing fraud with Lilly's similar erectile dysfunction drug, Cialis.

571. Pfizer's Celebrex (celecoxib) was initially approved by the FDA as an anti-inflammatory/pain therapy in 1998. The product is currently approved for the treatment of osteoarthritis, acute pain, rheumatoid arthritis, dysmenorrhea and ankylosing spondylitis. Unlike the anti-TNF drugs, Celebrex is primarily for symptomatic benefit and is not "disease-modifying".

572. In its early years of launch, Celebrex's US prescription uptake was robust. However, over the past decade, use of the drug has eroded considerably due to rising safety concerns. The product's label now includes an FDA "black box" warning regarding increased cardiac events (including strokes and heart attacks) and gastrointestinal events (bleeding, ulcers and perforation). Celebrex lost patent protection in the US in 2015.

573. According to IMS, US Celebrex prescription volume was declining sharply even prior to its 2015 US patent expiration, with volume down about -40% between 2006 and 2014.

574. Despite sharply eroding use, the AWP price of Celebrex increased more than four-

fold from $3.34 per 200 mg pill in early 2006 to $14.47 in mid-2018. See **Exhibit 19**.

575. Driven by these price increases, Pfizer's SEC-reports US sales of Celebrex rose from $1.577 billion in 2006 to $1.735 billion in 2014, despite markedly eroding clinical use. Without the price increases, US Celebrex sales would have been in the $950 million range in 2014.

576. All of Celebrex's price-driven US sales growth has been enabled by "service fee" fraudulent arrangements with the PBM Defendants. Overall, we estimate cumulative Celebrex fraudulent US sales of about $4.2 billion between 2006 and 2016. We estimate that 35% of this fraud has occurred in Medicare Part D.

577. Pfizer's Chantix (varenicline) was FDA-approved as an aid to smoking cessation treatment in 2006. Due to limited efficacy and safety concerns, use of Chantix has been relatively modest. The FDA label for Chantix includes a "black box" safety warning regarding serious neuropsychiatric events, including agitation, depression and suicidal ideation. Chantix competes with an array of other prescription and over-the-counter smoking cessation therapies, including numerous nicotine products.

578. According to IMS, the annual US prescription volume for Chantix declined by 29% between 2010 and 2014, but has rebounded over the past several years. Overall, we estimate that Chantix US prescription volume has decreased about -14% between 2010 and 2016.

579. According to Red Book, the AWP price of Chantix increased 4-to-5 fold from $1.92 per 1 mg tablet in early 2005 to $8.60 in mid-2018. See **Exhibit 19**.

580. Driven by these large price increases and a recent usage rebound, Pfizer's SEC-reported US Chantix sales have increased from $330 million in 2010 to $789 million in 2017. Without the price increases, US Chantix sales would be in the $290 million range in 2017.

581. Most of Chantix's price-driven US sales growth has been enabled by fraudulent

"service fee" arrangements with the PBM Defendants. Overall, we estimate cumulative Chantix fraudulent US sales of about $1.5 billion between 2010 and 2017. We estimate that 15% of this fraud has occurred in Medicare Part D, since quitting smokers are often younger in age.

582. Pfizer's Premarin (conjugated estrogen) is one of the longest-marketed US brand products, available since 1942. Pfizer began marketing Premarin following its 2009 acquisition of Wyeth Pharmaceuticals. Premarin is FDA-approved for the treatment of vasomotor symptoms due to menopause, vaginal atrophy and the prevention of osteoporosis.

583. Due to its complex formulation derived from horse urine, AB-rated, fully-substitutable generic versions of Premarin have yet to reach the US market, despite numerous development attempts.

584. In 1995, the combination hormonal product, Prempro (conjugated estrogen/medroxyprogesterone) was approved in the US. The progesterone component of Prempro decreases the uterine cancer risk associated with unopposed estrogen therapy.

585. Over the past decade the use of Premarin/Prempro, and the many other estrogen formulations available in the US, has declined sharply due to health and safety concerns. All estrogens now carry an FDA "black box" safety warning regarding cancer and cardiovascular risks.

586. According to IMS, combined annual US prescriptions for all Premarin/Prempro formulations has declined by about -57% just between 2010 and 2016, with more erosion back to 2006.

587. Despite sharply eroding use, the AWP price of all Premarin formulations has increased five-fold from $1.28 per pill in early 2006 to $6.42 in mid-2018. See **Exhibit 19**.

588. Driven by these severe price increases, Pfizer reported stable US Premarin sales,

despite severe erosion in clinical use. Pfizer's SEC-reported US Premarin sales were $949 million 2010, which modestly declined to $921 million in 2017. Without the price increases, US Premarin sales would have fallen sharply to the $360 million range in 2017.

589. All of Premarin's price-related US sales growth has been due to fraudulent "service fee" arrangements with the PBM Defendants. Overall, we estimate cumulative Premarin fraudulent US sales of nearly $2.725 billion between 2010 and 2017. We estimate that 30% of this fraud is attributable to Medicare Part D.

590. Pfizer's Pristiq (desvenlafaxine) was FDA-approved for the treatment of depression in 2008. Pristiq is a serotonin and norepinephrine reuptake inhibitor (SNRI). The usage of Pristiq has been moderate since launch due to the availability of a wide array of generic antidepressants offering similar clinical profiles. Former similar major US antidepressant brands that are now generically-available include Prozac, Zoloft, Paxil, Lexapro, Cymbalta and Effexor.

591. According to IMS, the annual US prescription volume for Pristiq has declined by about -29% between 2010 and 2016.

592. Despite declining use in a largely generic marketplace, the AWP price of a 50mg pill of Pristiq has increased more than three-fold from $4.09 per 50 mg pill in 2008 to $13.95 in mid-2018. See **Exhibit 19**.

593. Driven by these price increases, Pfizer's SEC-reported US sales of Pristiq increased from $405 million in 2010 to $578 million in 2016. Without the price increases, US Pristiq sales would be in the $275 million range in 2016. US Pristiq sales declined sharply in 2017, following its US patent expiration.

594. All of Pristiq's price-driven US sales growth has been enabled by fraudulent "service fee" arrangements with the PBM Defendants. Overall, we estimate cumulative Pristiq

fraudulent US sales of about $1.26 billion between 2010 and 2016. We estimate that 25% of this fraud has occurred in Medicare Part D.

595. Pfizer's Relpax (eletriptan) was FDA-approved for the acute treatment of migraines in 2002. Relpax acts as a serotonin receptor agonist. The usage of Relpax has been modest since launch due the availability of numerous other similar serotonin migraine therapies.

596. In recent years, patient usage of Relpax has eroded due to the availability of generics for the three former market-leading serotonin therapies, Glaxo's Imitrex (sumatriptan, 2009 patent expiry), Merck's Maxalt (rizatriptan, 2013 patent expiry) and Astra Zeneca's Zomig (zolmitriptan, 2013 patent expiry).

597. According to IMS and our estimates, the annual US prescription volume for Relpax has declined by about -24% between 2010 and 2016.

598. Despite eroding use, the AWP price of Relpax increased four-fold from $18.32, per 20 mg pill, in early 2006 to $74.73 in mid-2018. See **Exhibit 19**.

599. Driven by these price increases, Pfizer's SEC-reported US sales of Relpax have increased from $189 million in 2010 to $226 million in 2016. Without the price increases, US Relpax sales would be in the $145 million range in 2016.

600. All of Relpax's price-driven US sales growth has been enabled by fraudulent "service fee" arrangements with the PBM Defendants. Overall, we estimate cumulative Pristiq fraudulent US sales of about $420 million between 2010 and 2016. We estimate that 15% of this fraud has occurred in Medicare Part D.

LONG-STANDING PATTERN OF DEFENDANT SECRECY AND DECEIT

601. Avoiding the detection of a scheme of this magnitude and duration requires extreme secrecy and lack of transparency, which must be stringently coordinated at the executive suite

level.

602. Both the Manufacturer and PBM Defendants uniformly refuse to disclose any information in their SEC filings regarding their mutual financial arrangements, including contracts, rebates, "service fees" or any other transactions.

603. Specific to this scheme, we have found no discussion of BFSFs in any of the Defendants' SEC filings over the past decade, since the arrival of Medicare Part D. Failure to disclose this material information has enabled this scheme and led to severe financial and medical harm.

604. The extreme lack of financial disclosure in the PBM industry is legendary in the investment world and central to the pricing scheme. The PBM SEC disclosures regarding their source of profits are scant and often misleading.

605. For instance, the following is the only comment from Express Scripts in its 2015 10-K regarding its drivers of gross profit growth: "This increase is also due to better management of ingredient costs and formulary, as well as cost savings from the increase in the aggregate generic fill rate, partially offset by lower claims volume".

606. Similar to Express Scripts, none of the other three dominant PBMs, CVS Health, UnitedHealth Group and Humana, provides detailed disclosure of its sources of profits from prescription drugs.

607. Furthermore, the PBM Defendants provide minimal, if any, disclosure of the profit contribution of "specialty" drugs and Medicare Part D, the key growth driver in recent years.

608. With little verifiable financial information in the public domain, the senior executives from the Manufacturer and PBM Defendant intentionally disseminate a wide array deceitful, misleading and inaccurate information in order to deflect attention from their collusive

scheme. Key topics of deceit include drug rebates, price increases, Medicare Part D, patient assistance programs (PAPs) and drug coupons.

609. Both drug manufacturers and PBMs effectively utilize their closely-controlled trade organizations, the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Pharmaceutical Care Management Association (PCMA). These organizations are funded by industry, with numerous senior executives from the Defendants serving as board members.

610. We will highlight a couple examples of coordinated misinformation, which are indicative of the long-standing, nationwide collusive scheme.

611. A repeated strategy is the use of spurious and unverifiable internal or "paid consultant" research. For instance, in April 2016, the PhRMA and individual drug manufacturers aggressively utilized "research" from IMS that indicated that net price increases realized by US drug manufacturers declined sharply in 2015 to only 2.8%, despite average AWP price increases of 12% for the year. IMS Institute for Health Informatics, March 2016.

612. The pharmaceutical manufacturers, including executives of the Defendants, have widely attributed this net pricing decline to aggressive "rebate/discount" negotiations by PBMs, despite the data being counter to a wide array data indicating far higher pricing and lower manufacturer rebate trends (including the CMS data for Medicare Part D).

613. However, the footnotes of the IMS report indicate that their "cost savings" calculations included manufacturer patient assistance programs (PAPs) and "service fees", thereby intentionally exaggerating the "calculated discounts" to payers and beneficiaries.

614. The PAP impact was included at "retail" prices, rather than the far lower true manufacturing cost of the drugs.

615. Since PBM "service fees" are nearly universally not shared by the PBM Defendants

with payer clients, their inclusion in the "discount" calculations is intentional deceit.

616. The PBM industry and the PCMA routinely use similar deceitful tactics. In November 2011, the PCMA paid a consulting firm, Visante, to generate a report regarding drug coupons, an increasingly controversial topic. Many experts report that drug coupons cause patients to inappropriately use expensive brand drugs. How Copay Coupons Could Raise Prescription Drug Costs by $32 Billion Over the Next Decade. November 2011.

617. Not surprisingly, the "paid" research concluded that drug manufacturers were fully to blame for the abuse of drug coupons and that PBMs could do little about it since they did not have access to the prescription claims data. This conclusion is inaccurate and deceitful for extreme-priced "specialty" drugs, which now account for the majority of money spent on coupon programs.

618. The PBM Defendants dominate the specialty mail order pharmacy market, which now accounts for 80% of US "specialty" drug prescription volume. As such, the PBMs have full access to all claims data for their administered "specialty" prescriptions and could stop the use of coupons at any time in the interest of their private insurance clients.

619. Over the past several years, as US pricing scrutiny has escalated, the collusive pharmaceutical and PBM industries are increasingly "blaming" each other for drug massive drug price increases that have resulted from their mutual scheme. The manufacturers claim that they are keeping only small portion of price increases, while the PBMs are taking extraordinary profits through their "murky" and nontransparent business practices.

620. The PBMs, in turn, state that they have no control over drug pricing. Of note, both Defendant parties continue to focus on "rebates" as the key issue, while assiduously avoiding discussion of "service fees".

621. Regardless of the recent escalation in the deceitful "adversary" rhetoric,

manufacturers and PBMs have been, in reality, working closely together for the past two decades.

622. In the decade before Part D, PBMs made the majority of their profits from manufacturer rebates. Since Part D, PBMs have made the largest portion of their profits in collusive pricing scheme regarding manufacturer "service fees".

PART D REQUIREMENTS FOR "BONA FIDE SERVICE FEES (BFSFs)"

623. Indicative of the secrecy of this scheme, we have been unable to locate any public record of legislative discussion of BFSFs prior to Congressional passage of Part D into law. In fact, BFSFs are not even mentioned in the 416-page Medicare Modernization Act (MMA) of 2003, which enacted the Part D program. PUBLIC LAW 108-173, DEC. 8, 2003.

624. In addition, BFSFs are only cursorily mentioned in the subsequent Code Federal Regulations (CFR) governing the Part D program, in Sections §423.514 and §423.501.

625. Section §423.514 of the CFR establishes the exclusion of BFSFs, in sharp contrast to manufacturer rebates, from Part D "negotiated price" calculations.

626. In Section §423.514, among other reporting requirements, the regulations state: "Each entity that provides pharmacy benefits management services must provide to the Part D sponsor, and each Part D sponsor must provide to CMS, in a manner specified by CMS, the following: (4) The aggregate amount and type of rebates, discounts or price concessions (excluding bona fide service fees as defined in §423.501) that the PBM negotiates that are attributable to patient utilization under the plan".(Emphasis added)

627. Section §423.501of the CFR states: "Bona fide service fees means fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in

part to a client or customer of an entity, whether or not the entity takes title to the drug".

628. According to CMS, all BFSFs must pass the "Four-Part Test" in order to "qualify" for exclusion from Medicare Part D "negotiated price" calculations. 71 Fed. Reg. 69624, 69667-9. The first three parts of the test are:

629. the “itemized” service is actually performed;

630. the manufacturer would otherwise perform or contract for the service in the absence of the service contract, and;

631. the fee is not passed on in whole or in part to a client (i.e., it is kept by the PBM Defendant or other service providers).

632. However, the "Achilles Heel" facing both the Manufacturer and PBM Defendant in this scheme is the final criteria of the "Four-Part Test", which requires that all BFSFs be paid at "Fair Market Value" (“FMV”) commensurate with an "arm's length" transaction between unaffiliated parties.

633. The CMS regulations regarding the handling of BFSFs and the legal requirements of FMV in Medicare Part D have been unequivocally in place since the start of the program in 2006. Furthermore, since at least 2007, the handling of BFSFs and FMV has been virtually identical in the Medicaid, Medicare Part B and Medicare Part D drug programs.

634. In the Part D regulations, CMS places the legal onus on the drug manufacturers to justify that the fees represent "Fair Market Value" (“FMV”) for the services rendered. However, as mentioned previously, both the Manufacturer and PBM Defendant are liable under the FCA and the AKS for the fraudulent BFSFs and excessive drug costs in Medicare Part D.

635. CMS states: "manufacturers should appropriately determine fair market value and make reasonable assumptions consistent with adequate documentation that will support their

payment for these services at fair market rates sufficient that an outside party can determine the basis for the fair market value determination." (Emphasis added) 77 Fed. Reg. at 5332.

636. CMS has purposely kept its guidance regarding FMV vague due to concerns about potential fraud. CMS reiterated its position in its February 2012 proposed rule: "We continue to be concerned that these fees could be used as a vehicle to provide discounts, as opposed to fees at 'fair market value' for bona fide services. Thus, to avoid potential fraud concerns, we are retaining our definition, but we have chosen not to define 'fair market value' at this time." Federal Register, Vol 77, No 22, February 2, 2012.

637. CMS has made it clear that it considers all payments to service vendors, other than BFSFs, to be price discounts/concessions that must be included in Part D "negotiated price" calculations.

638. Per the Medicare Part D DIR ("Direct and Indirect Remunerations") Reporting Requirements for 2010 Payment Reconciliation, dated June 6, 2011: "CMS considers all remunerations received directly or indirectly from pharmaceutical manufacturers, with the exception of bona fide service fees (BFSFs), to be price concessions that serve to reduce the drug costs incurred by the Part D sponsor."

639. By law, any "service fee" amounts paid by the Manufacturer Defendants to the PBM Defendants and other Service Vendors in "excess" of FMV must be reported to CMS as price concessions (i.e., "Direct and Indirect Remuneration") which serve to lower drug costs in Medicare Part D.

640. As per CMS in 2011: "In the case of rebate administration fees or other amounts from pharmaceutical manufacturers that exceed fair market value, but otherwise meet the definition of a bona fide service fee, the differential between the rebate administration fee or other

amount and fair market value must be reported as DIR in column DIR #4." Final Medicare Part D DIR Reporting Requirements for 2010 Payment Reconciliation: Summary Report, dated June 6, 2011.

641. Legal precedent (American Lithotripsy Society v. Thompson, 215 F Supp. 2d 23 (200), US District Court, District of Columbia) has established that payments in excess of FMV are “payments for referral” and a violation of the Anti-Kickback Statute (AKS).

642. In 2006, CMS enacted regulations clarifying BFSFs. The regulations expressly re-affirmed that “service fee” payments must be for legitimate services rendered and thus not related to the price of the drug. Fed. Reg. 69624, 69668 (Dec 1, 2006) (relevant sections codified at 42. C.F.R. 414.802, 414.804).

643. In its 2007 final rule, CMS added that BFSFs should be "associated with the efficient delivery of drugs". In the rule, CMS interprets this standard to "encompass any reasonably necessary or useful services of value to the manufacturer that are associated with the efficient distribution of drugs." 71 Fed. Reg. at 69667-6.

644. The AKS requires that transactions be “commercially reasonable”. 69 Fed. reg. 16,093 (March 26, 2004) According to the statute's theory, most business transactions must be “commercially reasonable” or there would be no reason for them to occur.

645. Of note, the AKS considers “commercial reasonableness” of a financial transaction to be a separate and distinct determination compared to FMV. The AKS states: "If compensation is based upon comparables, assurance is required that the markets are not "distorted", and that compensation is "commensurate with the skill level and experience reasonably necessary to perform the contracted service". OIG Supplemental Compliance Program for Hospitals, p 4866-67.

646. In this scheme, the broad use of "percent of revenue" contracts, linked to massive price increases has corrupted and "distorted" the US pharmaceutical market. As per the AKS, a Defendant following these practices simply because others are doing it is not a viable defense. Each Defendant is individually responsible for ensuring, separately and distinctly, the appropriate levels of "commercial reasonableness" and FMV in its business transactions.

647. The AKS separately requires that, in any compensation arrangement, the payment must represent "reasonable compensation". 26 C.F.R. 1.162-7 (b) (3) (2004). The typical 7 to 8-fold increase in "service fee" compensation per patient for the "old" Defendant drugs, driven by massive price increases, fails this requirement by a wide margin.

648. We have determined that the large "service fees" paid, per patient per year, by the Defendant Manufacturers to the PBM Defendants for both oral "specialty" and "traditional" drug products represents excessive compensation far outside of FMV.

649. Although CMS has increased BFSF reporting requirements in recent years, the data still has important limitations. First, virtually all BFSF and DIR reporting is still done by the plan sponsor "insurance" legal entity in Part D and are only reported at the "aggregate" level (not by individual product).

650. To this day, CMS does not require direct reporting of BFSFs, or their FMV justification, by drug manufacturers. Furthermore, CMS apparently does not require direct reporting of BFSFs by PBM or specialty pharmacy legal entities operating in Part D. As such, the PBM Defendants could potentially conceal fraudulent BFSFs in their legally-separate, but wholly-controlled PBM and specialty pharmacy subsidiaries.

651. Given the varied opportunities to obscure illegal "service fee" payments, we anticipate an investigation of these fraud allegations must include a review of all economic

transfers between the Manufacturer and PBM Defendant, starting with their contractual arrangements. We would seek to obtain all forms of economic transfer from the manufacturers to the PBMs and their affiliates, including BFSFs, discounts, free goods, cost-sharing offsets, etc.

652. The CMS "Four-Part Test" requirement for manufacturers to "itemize" BFSFs by individual product and service is an important consideration in this case. Upon request by the government, such as in a fraud investigation, the Manufacturer Defendants must produce documentation of individual services actually provided by PBM Defendants for specific products and the FMV assessment methodology used to assign appropriate value.

REVIEW OF FAIR MARKET VALUE (FMV)

653. With CMS purposely not defining methods for BFSF FMV assessment in the Part D program, each drug manufacturer must determine its own process based upon acceptable practices in the private marketplace.

654. Although FMV assessment in the business world is designed to provide flexibility, a review of the topic reveals remarkable consistency in recommended approaches across both private and government entities.

655. The definition of FMV provided by the American Society of Appraisers has been generally accepted by both private industry and government agencies: "The price expressed in terms of cash equivalents, at which property would change hands between a hypothetical willing and able buyer and a hypothetical willing and able seller, acting at arm's length in an open and unrestricted market, when neither is under compulsion to buy or sell and when both have reasonable knowledge of the relevant facts". American Society of Appraisers Business Valuation Standard Glossary, Approved June 2005, Copyright 2005, American Society of Appraisers.

656. In the private sector, generally accepted valuation principles employee three

primary approaches to FMV assessment: the "Income", "Market" or "Cost" Approaches.

657. Using the "Income Approach", the FMV payment would be based upon the amount and timing of cash flows generated by the business, asset or service.

658. The "Income Approach" is typically not relevant for “services” provided by healthcare professionals (i.e., including PBM “service fee” agreements with manufacturers) because "these services cannot, and should not be, directly associated with cash flow." Helman, Saul B, DeLong, J., Navigant Life Sciences, "Fair Market Value is Critical in Implementing the Physician Payments in Implementing the Physician Payments Sunshine Act", 2012.

659. In the "Market Approach", FMV is determined by looking at the market prices of similar services. As such, a manufacturer may decide to determine the FMV of a “service fee” arrangement with a PBM/specialty pharmacy based upon the financial terms of competitor manufacturer/vendor relationships.

660. A "percent of revenue" arrangement is the most common form of "Market Approach" FMV methodology. However, some Manufacturer and PBM Defendant may utilize other contract terms, such as flat fees and lump sum payments, in abusive “service fee” arrangements, particularly if they seeking to avoid legal issues pertaining to "percent of revenue" arrangements.

661. The "Market Approach", including "percent of revenue" constructs, carries significant risk under the AKS.

662. These concerns were summed up in a 1992 letter from the OIG to the IRS: "Merely because another buyer may be willing to pay a particular price is not sufficient to render the price to be paid fair market value. The fact that a buyer in a position to benefit from referrals is willing to pay a particular price may only be a reflection of the value of the referral stream that is likely to

result from the purchase." Letter from D. McCarty Thorton, Associate General Counsel, Office of Inspector General (HHS) to T. J. Sullivan, Technical Assistant, off of the Associate Chief Counsel, Employee Benefits and Exempt Organizations, December 22, 1992.

663. In the "Cost Approach", the FMV of the service is based upon the specific cost of providing the service, plus a reasonable profit. In this methodology, the FMV should not exceed the cost to obtain substitute service from a third-party in an “arm's-length” transaction.

664. Our investigation and expert commentary clearly indicate that the straightforward "Cost Approach" is the most appropriate and accurate way to assess the FMV of “service fees” paid by manufacturers to PBMs and specialty pharmacies. First, FMV experts clearly state that FMV payments should be determined for a "service and not a person". Helman, Saul B, DeLong, J., Navigant Life Sciences, "Fair Market Value is Critical in Implementing the Physician Payments in Implementing the Physician Payments Sunshine Act", 2012.

665. In a September 2012 presentation, consultants from Huron Associates stated: "Once a fair market value range for an activity is determined, the amount should be multiplied by the volume of that activity for each type of service and added together to arrive at a fair market value range for the contract." Huron Life Sciences Presentation, "Determining the Bona Fide Nature of Fee-for-Service Arrangements", 9/27/12.

666. In the same presentation, Huron Life Sciences described the particulars of the appropriate “Cost Approach" for "bona fide" services. The “price for a bona fide service" can be thought of as an amount that covers:

a) “the direct cost of the service;
b) the overhead associated with delivering that service;
c) the cost of assets used up in the delivery of the service; and,
d) a reasonable return on the assets employed in the delivery of that service".

667. The appropriateness of the "Cost Approach" was verified by a wide array of industry experts at FMV of BFSF conference attended by Dr. Borzilleri in October 2013.

DIPLOMAT PHARMACY SEC FILINGS: TRUE LOW FMV OF "SERVICE FEES"

668. The SEC filings of the largest remaining independent specialty pharmacy, Diplomat Pharmacy, Inc., verify that the appropriate "arm's length" compensation to the PBM Defendants for providing manufacturer services should be very modest, even for "complex" specialty drugs.

669. According its public disclosures, Diplomat provides services for all the Defendant "specialty" drugs in this case. However, in comparison to the larger PBM Defendants, Diplomat has apparently historically lacked the negotiating leverage with drug manufacturers that would enable favorable "percent of revenue" service contract arrangements.

670. Despite offering specialty pharmacy services to manufacturers which they claim to be equal to, if not superior to, the PBM Defendants, Diplomat disclosed, in its Form S-1 filed with the SEC in July 2014 for its Initial Public Offering (IPO) that the company received minimal compensation from manufacturers for these "services".

671. As per page 18 of the S-1, Diplomat states: "We also provide a significant amount of direct and indirect services for the benefit of our pharmaceutical manufacturer customers and our patients in order to get access to specialty drugs, and our failure to provide services at optimal quality could result in losing access to existing and future drugs. In addition, we incur significant costs in providing these services and receive minimal service fees in return." (Emphasis added)

672. While Diplomat and likely other smaller specialty pharmacies, receive minimal compensation, the larger PBM Defendants are receiving large and escalating "percent of revenue" "fee" payments, tied to massive price increases, for the same Manufacturer Defendant "specialty"

drugs.

673. This wide discrepancy, between the PBM Defendants and smaller "arm's length" operators, indicates that the appropriate FMV "service fee" payments to the PBM Defendants should be a fraction of what they are currently receiving.

"PERCENT OF REVENUE" CONTRACTS NOT PROTECTED BY SAFE HARBORS

674. Our investigation indicates that "percent of revenue" Part D BFSF contractual arrangements between the Manufacturer and PBM Defendant are not protected by Office of Inspector General (OIB) Safe Harbors regarding "kickbacks".

675. The relevant OIG Safe Harbors in this matter pertain to Personal Services and Group Purchasing Organizations (GPOs).

676. On April 18, 2003, the OIG issued a document in the Federal Register entitled "OIG Compliance Program Guidance for Pharmaceutical Manufacturers" In the document, OIG states: "In addition, manufacturers may contract with purchasers to provide services to the manufacturer, such as data collection services. These contracts should be structured whenever possible to fit in the personal services safe harbor; in all cases, the remuneration should be fair market value, for legitimate, reasonable, and necessary services" (Emphasis added). Further details are provided in the "Personal Services and Management Contracts Safe Harbor". §1001.952.

677. The April 2003 OIG Pharmaceutical Manufacturer guidance states: "Any rebates or other payments by drug manufacturers to PBMs that are based on or otherwise related to, the PBM's customers' purchases potentially implicate the anti-kickback statute. Protection is available by structuring such arrangements to fit in the GPO Safe Harbor at 42 CFR 1001.952(j)."

678. GPOs are organizations that act as purchasing intermediaries that negotiate contracts between health care providers (primarily hospitals) and vendors of medical products and

services, including manufacturers, distributors and other suppliers.

679. The GPO Safe Harbor appears to be the only federal mechanism potentially affording specific protection for "service fee" contracts structured as a "percent of manufacturer revenues", albeit with significant limitations.

680. According to the April 2003 guidance, "That safe harbor (GPO) requires, among other things, that the payments be authorized in advance by the PBM's customer and that all amounts actually paid to the PBM on account of the customer's purchases be disclosed in writing at least annually to the customer." This information must be disclosed to the Secretary of Health and Human Services (HHS), upon request.

681. With consent of the entity (i.e., payer client), the GPO Safe Harbor states: "participating vendors from which the individual or entity will purchase goods or services will pay a fee to the GPO of 3 percent or less of the purchase price of the goods or services provided by that vendor."

682. In violation of the GPO Safe Harbor, in most instances, neither the manufacturer nor PBM Defendant is disclosing the contracts or amounts of "service fees" to either private insurance clients or CMS.

683. In addition, in many contractual arrangements, the PBM Defendants garner manufacturer "service fees" far in excess of the 3% GPO limit.

684. The Safe Harbor states that the GPO can neither be "wholly-owned by the GPO nor subsidiaries of a parent corporation that wholly owns the GPO (either directly or through another wholly-owned entity." Since the PBM Defendants wholly-own the PBM, specialty pharmacy and plan sponsor subsidiaries in most instances in Part D, the GPO Safe Harbor cannot apply in these predominant situations.

685. In February 2016, with the release of the AMP final rule and its related public commentary, CMS definitively stated that BFSFs are not protected by the GPO Safe Harbor. 42 CFR Part 447. While the AMP rule pertains to Medicaid, the regulatory requirements for BFSFs are identical in all government drug programs, including Part B and Part D.

686. As per the government reply below, drug manufacturers must determine the legitimacy of "service fee" arrangements via the Four-Part test, including a FMV determination.

687. As per page 5180 of the February 2016 AMP rule document: "Comment: A few commenters urged CMS to rely on the GPO safe harbor associated with the federal anti-kickback statute as it defines which fees would qualify as bona fide. The commenter stated that the final rule should state that a fee satisfying the anti-kickback statute safe harbor requirement meets the fair market value prerequisite and is a bona fide service fee".

688. CMS Response: "We believe that to adopt a categorical exclusion of administrative fees if they fall within the GPO safe harbor provisions would be inconsistent with our guidance regarding an actual determination as to whether or not the fee is bona fide because it would mean that the manufacturer has not evaluated the details of the specific arrangements regarding the services being performed. Additionally, we do not agree that we should adopt the safe harbor provisions associated with the federal anti-kickback statute as part of this rule as it does not address bona fide service fee determinations for purposes of determining included and excluded transactions related to a manufacturer's determination of AMP and best price."

PBM CLIENT CONTRACT INDICATE 'SERVICE FEE" FRAUD

1) EXPRESS SCRIPTS:

689. While manufacturer/PBM "service fee" contracts remain closely guarded by the

Defendants and outside the public domain, we have located several PBM/payer client relationships that indicate the fraudulent drug pricing scheme between the Defendant parties.

690. Our investigation has determined that PBM/payer client contract terms are highly standardized across the PBM industry, both in the private insurance market and Medicare Part D.

691. A good example is the April 2012 PBM contract between Express Scripts and the Oklahoma City Municipal Facilities Authority. Express Scripts, Inc., Pharmacy Benefit Management Agreement, signed December 10, 2012.

692. The Oklahoma City contract states: "In addition, ESI (Express Scripts) provides administrative services to formulary rebate contracted manufacturers, which include, for example, maintenance and operation of the systems and other infrastructure necessary for managing and administering the PBM formulary rebate process and access to drug utilization data, as allowed by law, for purposes of verifying and evaluating the rebate payments and for other purposes related to the manufacturer's products. ESI receives administrative fees from the participating manufacturers for these services. These administrative fees are calculated based on the price of the rebated drug or supplies along with the volume of utilization and do not exceed the greater of (i) 4.58% of the average wholesale price (AWP) or (ii) 5.5% of the wholesale acquisition cost (WAC) of the products."

693. Express goes on to highlight other fee opportunities from manufacturers in the Oklahoma City contract. The PBM contract further states: "In its capacity as a PBM company, ESI also may receive service fees from manufacturers as compensation for the performance of various services, including, for example, formulary compliance initiatives, clinical services, therapy management services, education services, medical benefit management services, and the sale of non-patient identifiable claim information. These services are not part of the formulary rebate and

associated administrative fees."

694. As such, the actual service fee payments from some manufacturers to Express Scripts may be considerably higher than the "4.5-5.5% of sales" range stated in the previous paragraph.

695. Further increasing Express Scripts' manufacturer “service fee” opportunity, the Oklahoma contract excludes both “specialty” drugs and its own specialty pharmacies from general contract terms.

696. Exhibit A-1 of the contract states: "Specialty products will be excluded from any price guarantees set forth in the Agreement. In no event will the Mail Service Pharmacy or Participating Pharmacy pricing terms specified in the Agreement, including, but not limited to, the annual average ingredient cost discount guarantees, apply to Specialty Products dispensed by Curascript”. (i.e., a wholly-owned specialty pharmacy subsidiary of Express Scripts)

697. The contract further states that Express Scripts' wholly-owned specialty pharmacy subsidiaries can make separate “service fee” arrangements with manufacturers. As per the Oklahoma contract: "ESI has several licensed pharmacy subsidiaries, including our specialty pharmacies. These entities may maintain product purchase discount arrangements and/or fee-for-service arrangements with pharmaceutical manufacturers and wholesale distributors. These subsidiary pharmacies contract for these arrangements on their own account in support of their various pharmacy operations. Many of these subsidiary arrangements relate to services provided outside the PBM arrangement and may be entered irrespective of whether the particular drug is on one of ESI's national formularies. Discounts and fee-for-service payments received by ESI's subsidiary pharmacies are not part of the PBM formulary rebates or associated administrative fees paid to ESI in connection with ESI's PBM formulary rebate programs."

698. With these numerous potential manufacturer "service fee" revenue streams, the PBM Defendants have the opportunity for vast, non-transparent compensation from manufacturers in both Part D and the private sector, especially for “specialty” drugs exhibiting severe price inflation.

699. In the Oklahoma City contract, Express Scripts directly admits its culpability to the “service fee” scheme. First, the contract states: "ESI and Sponsor shall comply with all applicable and existing federal, state and local laws, standards, codes, ordinances, administrative regulations and all amendments and additions thereto, pertaining in any manner to the work and/or services provided by this Agreement."

700. Second, under section 7.13 of the contract, entitled "Alignment of Interests", the agreement states: "ESI acknowledges and agrees (as represented by ESI's response to Sponsor's RFP (i.e., Request for Proposal) that its business model is to align its interests with those of Sponsor. ESI does not engage in any business with a pharmaceutical manufacturer that is designed to manipulate the price or cost of any Brand Drug or Generic Drug in a manner that adversely impacts the cost to Sponsor of providing pharmacy benefits to Members under this Agreement. In this regard, "adversely impacts" is intended to mean that Sponsor would be required to pay a higher price for a Brand Drug or Generic Drug than the market would otherwise provide if it were not for ESI's business arrangement with such pharmaceutical manufacturer."

701. In stark violation of this contract language, the client and CMS drug costs for a wide array of brand drugs have been exorbitantly escalated by the collusive fee arrangements between Express Scripts and drug manufacturers, linked to massive price increases.

702. As stated previously, the wide-ranging Part D liability for the PBM Defendants contrasts sharply with the situation in the private insurance market. Due to lack of ERISA fiduciary

responsibilities, the PBM Defendants have successfully fought of a wide array of private payer lawsuits over the past several decades.

2) CVS Health:

703. CVS Health client contracts also indicate fraudulent "service fee" arrangements with manufacturers based upon severe price inflation.

704. A clear example is CVS Health's May 15, 2008 agreement with the National Association of Counties. In a section entitled "Disclosure of Manufacturer Fees", this contract states: "Caremark may receive fees or other compensation from Manufacturers, including, without limitation, administrative fees not exceeding three percent of the aggregate cost of the pharmaceutical products dispensed to participants, and fees for property provided or services rendered to a Manufacturer (which may include providing physicians clinical messages consistent with the Performance Drug List, as defined below). Caremark's specialty pharmacies may also receive fees from the Manufacturers for products and services provided …The term Rebate as used in this Agreement does not include these fees and discounts which belong exclusively to Caremark or Caremark's mail order or specialty pharmacies, respectively."

705. All reimbursement in the Nation Association of Counties contract was based upon discounts to the Average Wholesale Price (AWP), with no protection from price increases.

706. Caremark provided definitive commentary regarding its handling of manufacturer fees during the 2007 bidding process for a contract to manage pharmacy benefits for the Maryland State Employee and Retiree Health and Welfare Program.

707. In this contract, Maryland sought full "pass-through" to the State for all manufacturer compensation to the PBM, including rebates and "service fees".

708. During the Maryland negotiations, the State asked CVS Health to confirm the

following contract provision: "The Contractor (i.e., PBM) selected shall not retain any revenue (attributable to the State's business) from pharmaceutical manufacturers or wholesalers, including, but not limited to data fees, access fees, market share fees, rebates, formulary access fees, administrative fees or marketing grants." Before the Maryland State Board of Contract Appeals, Docket Nos. MSBCA 2544, 2548, & 2565, March 2007.

709. Caremark replied in writing as follows: "Caremark agrees to the retail, mail, specialty, market share and rebated components. The following further explains Caremark's positioning on passing through service and data fees: Service fees that Caremark receive from pharmaceutical manufacturers include fees that Caremark may receive in connection with programs offered by Caremark, such as physician or participant education programs; compliance and persistency programs; and communications to healthcare professionals. These fees that are paid to Caremark are not paid to or allocated by Caremark on a client-specific basis. Rather, these fees are paid to reimburse Caremark for its service program offerings. For these reasons, Caremark does not disclose to its clients detailed information regarding service fees received and does not share those with its clients." (Emphasis added)

710. The Maryland Procurement Officer wrote that he "did not understand Caremark's response". He also stated that he found the response to be "purposely confusing" and interpreted Caremark's response to mean that "Caremark was holding back money that he wanted to get for the State".

711. Caremark did not provide greater clarity on these statements despite several requests. Maryland, in turn, awarded the Maryland contract to another vendor despite Caremark's being the lowest bid.

712. These CVS Health disclosures indicate that manufacturer "percent of revenue"

service fee contracts are set at a national level and not determined by the specific service needs of clients.

713. In the "County" contract, CVS Health certified that it "shall not violate the federal anti-kickback statute…with respect to the performance of its obligations under this agreement."

PHYSICIAN INTERVIEWS: LIMITED PBM DEFENDANT CLINICAL ROLE

714. Our discussions with physicians indicate that the clinical claims of the PBM Defendants greatly overstates their limited role in day-to-day patient care. As part of this investigation, Dr. Borzilleri conducted interview with 20-25 leading physicians in the multiple sclerosis, rheumatoid arthritis and cancer therapeutic areas.

715. In virtually all instances, the physicians indicated that the PBM Defendants primary role was to fill/deliver prescriptions and sometimes coordinate financial assistance. The need for patient financial assistance is now ubiquitous for “specialty” drugs after years of vast price inflation.

716. According to the physicians, for a patient newly-started on an injectable multiple sclerosis or anti-inflammatory “specialty” drug, their medical staff provides virtually all clinical support.

717. For the majority of stable patients chronically taking the long-marketed “specialty” drugs at the center of this case, the physicians reported minimal clinical involvement of PBMs/specialty pharmacies. One physician described the clinical claims of PBM/specialty pharmacies as a "gimmick to justify themselves."

718. In fact, numerous physicians stated that attempts at clinical intervention by centralized PBM/specialty pharmacy staff is often harmful, since the organizations typically have no in-person contact with these complex patients. One physician tersely stated, “If patients have a

problem with their CML (chronic myeloid leukemia) drug, they call me, not an 800 number at a PBM or a specialty pharmacy".

719. Conversations with physician experts uniformly indicated that PBM/specialty clinical services were even more scant for most oral "specialty" drugs. These physician discussions indicate a particularly high risk of "sham" services with "percent of revenue" service agreements for oral "specialty" drugs, particularly those linked to massive price inflation, such as the CML therapies in this case.

720. Prior to Medicare Part D, "service fees" were primarily employed for complex "specialty" patients, not for those treated with "traditional" drugs. We expect discovery to uncover even less legitimate "support services" for the Defendant "traditional" drugs.

PART D ORIGINS OF THE "SERVICE FEE" SCHEME

721. Before Medicare Part D, the dominant PBMs made virtually all their profits from the portion of "rebates" they "retained" from their negotiations with manufacturers on behalf of their private insurance clients.

722. In the private sector, aggressive PBM "rebate" negotiations with manufacturers were essential for controlling drug costs and preventing severe price increases. As compensation, the PBM kept (i.e., "retained") a significant, but often secretive, portion of these rebates.

723. Concerns regarding potential manufacturer/PBM collusion regarding "rebates" led to several major PBM lawsuits and settlements just as Medicare Part D was coming to fruition. On September 7, 2005, a Settlement Agreement was entered into between the United States, the PBM Advanced PCS and three Relators (Brown, Waite and Schulmann). In the settlement, AdvancePCS paid the sum of $137.5 million to resolve allegations brought forth by the US government.

724. On March 24, 2004, Advance PCS became a wholly-owned subsidiary of Caremark

Rx, Inc. Subsequently, on March 22, 2007, Caremark Rx merged with CVS to form CVS Caremark (now renamed CVS Health), one of the largest PBM Defendants.

725. The Justice Department made a similar Settlement Agreement in 2006 with another PBM, Medco Health Solutions. Medco merged with PBM Defendant Express Scripts in April 2012.

726. Despite these and other legal matters, as well as widespread concerns about their business practices, last decade PBMs were charged with the central role of "negotiating" in good faith with drug manufacturers on behalf of beneficiaries and taxpayers in the then new Medicare Part D program.

727. Cognizant of the central role of "manufacturer rebates" in the private insurance sector, Congress legislated assuming similar dynamics in the Part D program. Congress expected PBMs to aggressively negotiate with manufacturers for rebates/discounts on behalf of Part D beneficiaries and to be compensated by "retaining" a portion of the savings.

728. Congress required full disclosure of "rebates", including the portion kept by the PBMs, and their deduction from Part D "negotiated" prices in order lower drug costs for beneficiaries and the program. As such, compensation of PBMs by manufacturers via "rebates" in Part D would lead to lower drug prices and lower future industry profits, particularly regarding the competitively-challenged Defendant products.

729. Part D also requires full disclosure of brand drug pharmacy "price spreads", thereby limiting another prior key source of revenues/profits for the dominant PBMs. The abuse of brand drug "price spreads" was the central focus of the wide-ranging Average Wholesale Price (AWP) litigation, which resulted in more than $3 billion in pharmaceutical industry Qui Tam and RICO settlements.

730. In sharp contrast to rebates, legitimate BFSFs from manufacturer to PBMs (and other service providers) are the only major financial item excluded from government drug price calculations, including from Part D "negotiated" prices.

731. PBM compensation via BFSFs would lead to lower rebates and higher drug prices for both collusive partners. In fact, BFSFs became the only pathway for significant non-transparent payments between manufacturers and PBMs/specialty pharmacies in the Part D program.

732. By linking the "service fee" model to vast drug price increases, both manufacturers and PBMs could garner staggering profits. The vast majority of the rising drug costs would be borne primarily by taxpayers in Part D (via the program's various subsidies) and by largely unaware clients in the private sector.

733. Obviously, this new business model is counter to the intent of the Part D program, which sought legitimate negotiation between PBMs and manufacturers and affordable drugs costs for beneficiaries and taxpayers.

734. It is not surprising that the Defendants quickly pursued their own self-interest by secretly switching from the "rebates" to the "service fee" business model with the arrival of Medicare Part D. What is surprising is the astounding magnitude to which they have advanced the scheme.

735. Our investigation indicates that both the design of Part D and industry competitive threats contributed to the Defendants' aggressive pursuit of this fraudulent pricing scheme.

736. Most importantly, massive US brand drug patent expirations over the past decade decimated the prior largely secretive PBM "rebate"-based compensation model.

737. Starting around the time of Part D's arrival, virtually all the top brand drugs in the former top-spending primary care therapeutic categories lost patent protection, including the

cholesterol lowering, anti-hypertensive, antidepressants, anti-ulcer and antihistamines drug segments. As a result, generics now account for 90+% of US prescription volume, compared to about 50% a decade ago.

738. These patent expirations left the biopharmaceutical industry, but especially the Manufacturer Defendants, increasingly dependent upon a small number of remaining brand drugs, many of which also faced severe competition from new entrants.

739. The PBM financial opportunity from manufacturer brand drug rebates, their prior primary source of profits, also plummeted along with the widespread patent expirations.

740. Unfortunately, to the extreme detriment of the American public, rather than accepting the sharply deteriorating competitive market reality, the senior executives at these Defendant companies intentionally chose a fraudulent path for their corporate and personal financial gain.

741. We suspect that the astounding stock-based compensation packages for these senior executives, most of whom have been employed for the duration of the scheme, has been a key factor driving the abuse to the current stratospheric heights.

742. The increasing reliance of the Defendants upon high-cost "specialty" drugs for revenue and profit growth has been a key driver of the escalating scheme. After the massive wave of traditional US patent expirations over the past decade, many of the few remaining brand drugs are extreme-priced and highly-profitable "specialty" drugs, such as the Defendant products for rheumatoid arthritis and cancer.

743. Furthermore, the lax Part D definition of "specialty" drugs, based solely on price without any criteria for complexity or legitimate support needs, helped advance the scheme.

744. Most of the long-marketed drug Defendant brand drugs were widely and

chronically self-administered successfully, at far lower prices, by patients long before the illicit shift to the "service fee" based PBM compensation model.

745. As such, the purpose of this shift in "compensation model" was clearly to generate profits for the collusive partners, not to provide better care or lower drug costs for Part D and its beneficiaries.

746. Primarily driven by massive price increases on older drugs, "specialty" drugs now account for about 35-40% of US drug spending (up from about 10-15% at the start of Part D), while accounting for only 1-2% of overall US prescription volume (but about 10-20% of the shrinking US brand drug volume).

747. This price collusion scheme has masked and offset a tremendous drug cost-savings opportunity over the past ten years for American taxpayers and private employers, but especially in the Medicare Part D program.

748. If not for the massive price increases for the relatively few remaining US brand drugs, especially of the "specialty" variety, American taxpayers, employers and employees would have benefited from a sharp erosion in drug costs over the past decade due to massive patent expirations.

749. These dynamics are clearly reflected in the spending trends for the Medicare Part D program itself. According to CMS's own data, the average drug costs for the majority of relatively healthy Part D beneficiaries (i.e., those not needing extreme-priced "specialty" drugs) decreased by an astounding 43% (i.e., annual "Direct Subsidies" per beneficiary) between 2006 and 2014. Medicare Trustees Report, 2015.

750. Ironically, both the pharmaceutical and PBM industries frequently cite the Part D program as a glowing example of "free market" success and have recommended it as a "model"

for controlling drug spending in other segments of the US market.

PART D LEGISLATIVE HISTORY AND KEY GOVERNMENT DATA

751. When the Medicare Part D program began, both legislators and CMS expected private competition to generate significant cost savings for seniors and to hold down drugs prices.

752. In October 2003, as Congress was debating the Medicare Part D legislation, President George W. Bush claimed: "The best way to provide seniors with modern medicine, including prescription drugs coverage...is to give them better choices under Medicare. If seniors have choices, health plans will compete for their business by offering better coverage at more affordable prices." The White House, President Calls on Congress to Complete Work on Medicare Bill (Oct. 29, 2003).

753. In November 2003, Secretary of Health and Human Services, Tommy Thompson, stated: "Health insurance companies are going to get into this market...The pharmaceutical benefit managers (PBMs) who will be taking over purchasing of the drugs are going to be able to purchase in bulk with the pharmaceutical companies and hold down prices." (Emphasis added) The Big Story with John Gibson, Fox News Network (Nov. 26, 2003).

754. Key government officials actually suggested Medicare Part D drug cost savings would be even greater than in other federal drug programs, such as Medicaid.

755. While awaiting implementation of the program, in September 2004, Medicare Administrator Mark McClellan claimed that the private insurers would be able to obtain "the best" prices for seniors. He stated: "Our approach is expected to provide the best discounts on drugs, discounts as good or better than could be achieved through direct government negotiation." (Emphasis added) Testimony of Dr. Mark McClellan, Senate Finance Committee, Hearing on The

Medicare Prescription Drug Benefit, 109th Cong. (Sept. 14, 2005).

756. Legislative proponents and CMS clearly expected significant "negotiated" rebates/price concessions from drug manufacturers to be the primary method to limit elderly drug costs, to prevent severe brand drug price inflation and to compensate PBMs and other service vendors for their efforts in the Medicare Part D program.

757. Our investigation has found no public evidence of legislative debate regarding the role of "Bona Fide Service Fees" ("BFSFs") in Medicare Part D, with the issue remaining largely out of the public eye even now, more than a decade since the program's inception.

758. Counter to these expectations, considerable brand drug inflation in Medicare Part D commenced as soon as the program was implemented in January 2006.

759. According to CMS's own data reported in comments to a January 2010 General Accounting Office (GAO) report (GAO-10-242): "An internal CMS analysis revealed a more than 30 percent increase in the price indices of brand name drugs (both specialty and non-specialty tier) between January 2006 and October 2009."

760. In addition, counter to the CMS expectations, the percentage rate of rebates in Medicare Part D have been modest compared to other federal drug programs. Since inception, manufacturer rebates have averaged about 10%, with a modest increase to the 15% range in recent years. Medicare Trustee Annual Reports.

761. Compared to Part D, manufacturer rebates in the Medicaid program have been far larger, averaging 34% of program spending for the years 2006 through 2009. OIE-03-10-00320, Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicaid Part D, August 2011.

762. The far larger rebate proportion in Medicaid is because its statutes, in sharp contrast

to Medicare Part D, require that manufacturers provide additional rebates to CMS for any revenues generated by brand drug price increases on marketed products greater than general inflation (CPI-U, Consumer Price Index-Urban).

763. With ongoing severe Part D price inflation, OIG's most recent comparison of Medicaid and Medicare Part D indicated further divergence in rebate trends. For the year, 2012, rebates for the top-spending 200 brand drugs in Medicare D were 15% of the program's spending versus 47% for Medicaid. OIE-03-10-00650, Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin. Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicaid Part D, April 2015.

764. In March 2011, the Office of Inspector General (OIG) of the Department of Health and Human Services released a report entitled "Concerns with Rebates in the Medicare Part D Program". OIG HHS Report, OEI-02-08-00050, March 2011. The OIG analysis was based on all Part D sponsor rebate reports and plan bid data for 2008, as well as an in depth review of six selected sponsors.

765. The OIG report disclosed that Medicare Part D sponsors reported receiving $6.5 billion in drug manufacturer rebates in 2008, corresponding to approximately 10% of total gross Part D drugs costs of $63 billion for the year.

766. However, central to these fraud allegations and contrary to legislative expectations, PBMs "retained" less than 1% or only $24 million of the $6.5 billion (Emphasis added) in total manufacturer rebates reported to CMS in plan sponsor "Direct and Indirect Remuneration" ("DIR") reports for 2008.

767. In addition, 61% of plan sponsors reported that PBMs retained no Part D rebates in 2008.

768. As such, counter to legislative and public expectations, PBMs received minimal rebate compensation from drug manufacturers in 2008. Of note, this OIG report is the only federal document we have been able to locate which discusses manufacturer rebates "retained" by PBMs in the Part D program.

769. Since BFSFs were, by law, the only significant payments excluded from Part D sponsor DIR reports in 2008, virtually all PBM compensation for that year, beyond the minimal reported “retained” rebates, came in the form of BFSFs from manufacturers.

770. Additional direct CMS data confirms both extreme price increases and very low level of rebates for many high-cost “specialty” drugs in Part D.

771. In January 2010, the General Accounting Office (GAO) released a report (GAO-10-242), entitled: Medicare Part D – Spending, Beneficiary Cost Sharing, and Cost Containment Efforts for High-Cost Drugs Eligible for Specialty Tier”. The study analyzed “specialty” drug pricing and manufacturer price concession trends in the first three years of Part D, 2006 through 2008.

772. In the analysis, the GAO obtained “specialty” drug pricing and price concession data for 20 key specialty drugs from 7 large plan sponsors, which represented 51% of all Medicare Advantage Part D enrollment and 67% of standalone Part D enrollment in 2008.

773. In the report, the GAO identified ten chronic conditions commonly treated with “specialty” drugs; then selected two therapies for evaluation from each therapeutic category.

774. For all reviewed “specialty” drugs, the GAO found the level of discounts/rebates was below the 9-11% average in the Medicare Part D program throughout the 2006-2008 period. In addition, the Medicare Part D costs per patient had risen considerably for major “specialty” drugs, due to severe price inflation.

775. In the multiple sclerosis category, negotiated discounts for Biogen's Avonex were only 1.1-2.6% of list price, despite a 35% price increase over the two years. Discounts for Teva's MS therapy were modestly higher, at 6.2-8.0% of list price during the period, with a 26% increase in cost of therapy over the two years.

776. In the anti-TNF category, negotiated discounts for AbbVie's Humira were in the 6.1-8.2% of list price range, with 9% price inflation over the two years. For Amgen's Enbrel, negotiated discounts were lower, at 2.0-3.7% of list price, with 7% price inflation between 2006 and 2008.

777. In the cancer space, no negotiated discounts were provided in any year for Novartis' Gleevec and Roche's Tarceva (an oral drug for lung cancer), despite 24% and 13% price escalation, respectively, between 2006 and 2008.

778. The magnitude of price increases for the above noted "specialty" drugs and many other brand products has greatly accelerated since this dated GAO study.

MEDCO SEC FILINGS: LONG-STANDING, INTENTIONAL "SERVICE FEE" FRAUD

779. Prior to its 2012 merger with PBM Defendant Express Scripts, Medco Health Solutions was the largest independent PBM operating in the US.

780. As part of a 2004 settlement of a prior Qui Tam case and a related (OIG) Corporate Integrity Agreement, Medco provided unique and instructive financial disclosures in its 2003-2011 SEC 10-K filings regarding the burgeoning "service fee" scheme.

781. For the fiscal years 2003 through 2011, Medco disclosed both overall brand manufacturer rebates, as well as the amount of rebates the PBM "retained". Furthermore, Medco also provided disclosures regarding its "service fee" contractual arrangements with drug

manufacturers.

782. The 10-K disclosures indicate that Medco quickly and secretly began shifting away from a "manufacturer rebate"-based compensation model towards a primarily "service fee"-based model in the private insurance market upon the 2003 passage of the Medicare Part D legislation. Furthermore, the vast majority of the transition was complete by 2006 when Part D went into effect.

783. In 2003, Medco "retained" $1.6 billion, or 54% of all brand rebates from manufacturers, which accounted for more than 100% of Medco's gross profits for the year.

784. By 2006, Medco "retained" only $670 million, or 20% of all brand rebates, which accounted for only 28% of surging gross profits for the year.

785. In 2011, Medco's retained a similar magnitude of rebates ($757 million), which represented only 16% of exploding operating profits for the year.

786. For Medco overall, gross profits rose 60% from $1.5 billion in 2003 to $2.4 billion in 2006 and then nearly doubled in the next five years to $4.6 billion in 2011, despite a sharp drop in the contribution from "retained" manufacturer rebates.

787. These financial disclosures bluntly indicate that Medco was completely dependent upon manufacturer rebates for its profits at the time of Part D's legislative passage. In fact, in 2003, with "retained" manufacturer rebates, the remainder of Medco's operation, inclusive of its generic business, was unprofitable in 2003.

788. As the largest PBM in the US in 2003 by a wide margin, these Medco financials infer that manufacturer rebates were the dominant profit driver throughout the PBM industry in 2003.

789. In 2003, as the market leader, Medco had by far greatest generic procurement

negotiating leverage and the most efficient mail order operations.

790. If Medco's operations in 2003, excluding "retained" brand rebates, were unprofitable, smaller PBMs were either similarly dependent on manufacture brand rebates for profits or were minimally profitable at best.

791. Medco attributed its remarkable business transformation and profit growth between 2003 and 2011 to gains in its generic business.

792. Medco stated in its 2004 10-K: "the impact on profitability from the increase in generic utilization, particularly in mail order, more than offsets the impact from lower rebate retention on brand name prescriptions."

793. Medco suggested a wider range of profit contributors in its 2006 10-K, stating: "the gross margin effect of overall higher rebate sharing levels is partially mitigated by other elements of pricing including higher claims processing, administrative and other client service fees, higher generic dispensing rates, and increased specialty volumes."

794. In its final 2011 10-K prior to the Express Scripts merger, Medco reiterated its ongoing dependence on generics for profits: "Our future success will be largely dependent on our ability to drive mail-order volume and increased generic penetration rates in light of the significant brand-name drug patent expirations expected to occur over the next several years."

795. Medco never mentioned in its SEC filings a shift in compensation mechanisms for brand drugs from manufacturers towards "service fees" or any impact from Medicare Part D.

796. Based upon its own financial disclosures, Medco's claims regarding accelerating generic profitability between 2003 and 2011 would appear to be mathematically impossible.

797. Excluding "retained" brand drug rebates, Medco reported an astounding increase in its annual gross profits from a -$71 million loss in 2003 to a $3.9 billion profit in 2011.

798. With Medco's generic segment apparently unprofitable in 2003, the implied vast transformation in this business segment would appear unfeasible.

799. In reality, the only viable explanation for this profit transformation is the clandestine shift from a PBM compensation model based on brand manufacturer rebates to one based upon "service fees" (driven primarily by massive price increases), as a direct result of the Medicare Part D financial incentives.

800. With the increased brand "spread" and "rebate" transparency requirements in Part D, "service fees" became the only mechanism for large-scale "hidden" payments between drug manufacturers and PBMs. Medco secretly began the transition in the private insurance sector prior to the 2006 enactment of Part D, without any public disclosure.

801. There can be little doubt that other PBMs followed the lead of the market leader, Medco, in this secretive profit transition.

802. The Medco financial disclosures indicate a well-orchestrated, intentional systemic collusive scheme that has caused unimaginable public harm, now more than 13 years in duration.

803. Of note, Medco disclosed that its manufacturer "service fee" contracts with drug manufacturers were calculated as a "percent of revenues", inclusive of price increases.

804. Several of Medco's 10-Ks, including the 2006 document states: "Our contracts with manufacturers provide us with rebates and fees for prescription drugs through our mail-order and retail pharmacy networks, discounts for prescription drugs we purchase and dispense from our mail-order pharmacies, and performance-based fees associated with certain biopharmaceutical drugs. Rebates and fees are generally calculated as a percentage of the aggregate dollar value of a particular drug that we dispensed, based upon the manufacturer's published wholesale price for that drug".

805. In closing, the information in this Complaint all points to a singular conclusion. Namely, that the vast "inexplicable" price inflation for the Defendant brand drugs, and many others in the US marketplace, has been caused by this intentional, long-standing, secretive and collusive "service fee" scheme. After five-plus years of intensive investigation, we conclude that there is no other viable explanation.

CLAIMS ON BEHALF OF THE UNITED STATES OF AMERICA

COUNT ONE

False Claims Act

31 U.S.C. §§3729(a)(l) and (a)(2)

(Against All Defendants)

806. Plaintiff repeats and alleges each and every allegation contained in the paragraphs above as though fully set forth herein.

807. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

808. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to officers, employees or agents of the United States Government for payment or approval, within the meaning of 31 U.S.C. §3729(a)(1).

809. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false or fraudulent records and statements, and omitted material facts, to get false or fraudulent claims paid or approved by the United States Government, within the meaning of 31 U.S.C. §3729(a)(2).

810. The United States, unaware of the falsity of the records, statements and claims made or caused to be made by the Defendants, paid and continues to pay the claims that would not be

paid but for Defendants' unlawful conduct.

811. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

812. Additionally, the United States is entitled to the maximum penalty of $11,000 for each and every false and fraudulent claim made and caused to be made by Defendants arising from their unlawful conduct as described herein.

COUNT TWO

False Claims Act

31 U.S.C. §3729(a)(3)

(Against All Defendants)

813. Plaintiff repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

814. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

815. By virtue of the acts described above, Defendants conspired with others known and unknown, including without limitation Service Vendors, to defraud the United States by inducing the United States to pay and/or approve false and fraudulent claims, within the meaning of 31 U.S.C. §3729(a)(3). Defendants, moreover, took substantial steps in furtherance of the conspiracy, inter alia, by making false and fraudulent statements and representations, by preparing false and fraudulent records, and/or by failing to disclose material facts.

816. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

817. Additionally, the United States is entitled to the maximum penalty of $11,000 for each and every violation of 31 U.S.C. §3729(a)(3) as described herein.

COUNT THREE

Federal False Claims Act

31 U.S.C.§3729(a)(7)

(Against All Defendants)

818. Plaintiff repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

819. This is a claim for penalties and treble damages under the Federal False Claims Act.

820. By virtue of the acts described above, including without limitation Defendants' overpayment of BFSFs in lieu of rebates, which would have reduced the ultimate cost reimbursed by the federal government under Medicare Part D, to Service Vendors, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States Government, within the meaning of 31 U.S.C. §3729(a)(7).

821. As a result, money was lost to the United States through the non-payment or non-transmittal of money from foregone discounts and rebates to which the United States was entitled and owed by the Defendants, and other costs were sustained by the United States.

822. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

823. Additionally, the United States is entitled to the maximum penalty of up to $11,000 for each and every false record or statement knowingly made, used, or caused to be made or used to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States.

COUNT FOUR

Federal False Claims Act

31 U.S.C. §§3729(a)(l) and (a)(2)

(Against All Defendants)

824. Plaintiff repeats and alleges each and every allegation contained in the paragraphs above as though fully set forth herein.

825. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

826. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to officers, employees or agents of the United States Government for payment and/or approval, within the meaning of 31 U.S.C. §3729(a)(1) by paying BFSFs as illegal remuneration to Service Vendors (primarily PBMs and their specialty pharmacy subsidiaries in Medicare Part D) in order to induce purchase of Defendants' drugs which were then reimbursed by the federal government under Medicare Part D in violation of the Anti-Kickback Statute.

827. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false or fraudulent records and statements, and omitted material facts, to get false or fraudulent claims paid and/or approved by the United States Government, within the meaning of 31 U.S.C. §3729(a)(2) by paying BFSFs as illegal remuneration to induce Service Vendors to purchase Defendants' drugs which were then reimbursed by the federal government under Medicare Part D in violation of the Anti-Kickback Statute.

828. The United States, unaware of the falsity of the records, statements and claims made or caused to be made by the Defendants, paid and continues to pay the claims that would not be paid but for Defendants' unlawful conduct.

829. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

830. Additionally, the United States is entitled to the maximum penalty of $11,000 for each and every false and fraudulent claim made and caused to be made by Defendants arising from their unlawful conduct as described herein.

COUNT FIVE

California False Claims Act Cal

Gov't. Code §12651(a)(7)

(Against All Defendants)

831. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

832. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the "Bona fide Service Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of California via Federally-mandated, non-recourse "Clawback" payments for Defendants' drug costs in the Medicare Part D program.

833. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of California, within the meaning of Cal Gov't. Code §12651(a)(7). The State of California has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT SIX

Colorado Medicaid False Claims Act

Colo. Rev. Stat. §§ 25.5-4-303.5 through 25.5-4-310

(Against All Defendants)

834. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

835. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the "Bona fide Service Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Colorado via Federally-mandated, non-recourse "Clawback" payments for Defendants' drug costs in the Medicare Part D program.

836. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Colorado. The State of Colorado has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT SEVEN

Connecticut False Claims Act

Conn. Gen. Stat. § 17b-301b(a)(7)

(Against All Defendants)

837. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

838. During the Relevant Time Period, the Manufacturer Defendants and the PBM

Defendants were aware of their obligations to make and to use truthful records or statements regarding the "Bona fide Service Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Connecticut via Federally-mandated, non-recourse "Clawback" payments for Defendants drug costs in the Medicare Part D program.

839. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Connecticut, within the meaning of Conn. Gen. Stat. § 17b-301b(a)(7). The State of Connecticut has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT EIGHT

Delaware False Claims And Reporting Act

6 Del Code §1201(a)(7)

(Against All Defendants)

840. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

841. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the "Bona fide Service Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Delaware via Federally-mandated, non-recourse "Clawback" payments for Defendants' drug costs in the Medicare Part D program.

842. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Delaware, within the meaning of 6 Del. Code §1201(a)(7). The State of Delaware has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT NINE

Florida False Claims Act

Fla. Stat. Ann. §68.082(2)(g)

(Against All Defendants)

843. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

844. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the "Bona fide Service Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Florida via Federally-mandated, non-recourse "Clawback" payments for Defendants' drug costs in the Medicare Part D program.

845. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Florida, within the meaning of Fla. Stat. Ann. §68.082(2)(g). The State of Florida has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TEN

Georgia False Medicaid Claims Act

Ga. Code Ann. §49-4-168.1(7)

(Against All Defendants)

846. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

847. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the "Bona fide Service Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Georgia via Federally-mandated, non-recourse "Clawback" payments for Defendants drug costs in the Medicare Part D program.

848. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Georgia, within the meaning of Ga. Code Ann. §49-4-168.1 (7). The State of Georgia has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT ELEVEN

Hawaii False Claims Act

Haw. Rev. Stat. §661-21(a)(7)

(Against All Defendants)

849. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

850. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the "Bona fide Service Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Hawaii via Federally-mandated, non-recourse "Clawback" payments for Defendants' drug costs in the Medicare Part D program.

851. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Hawaii, within the meaning of Haw. Rev. Stat. §661-2l(a)(7). The State of Hawaii has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWELVE

Illinois Whistleblower Reward

And Protection Act

740 Ill. Comp. Stat. §175/3(a)(7)

(Against All Defendants)

852. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

853. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the "Bona fide Service Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Illinois via Federally-

mandated, non-recourse "Clawback" payments for Defendants' drug costs in the Medicare Part D program.

854. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Illinois, within the meaning of 740 Ill. Comp. Stat. §175/3(a)(7). The State of Illinois has thereby suffered actual damage s and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT THIRTEEN

Indiana False Claims and
Whistleblower Protection Act
IC 5-11-5.5-2(b)(6)
(Against All Defendants)

855. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

856. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the "Bona fide Service Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Indiana via Federally-mandated, non-recourse "Clawback" payments for Defendants' drug costs in the Medicare Part D program.

857. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Indiana, within the meaning of IC 5-11-5.5-2(b)(6).

The State of Indiana has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT FOURTEEN

Iowa False Claims Act

Iowa Code §§ 685.1 through 685.7

(Against All Defendants)

858. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

859. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the "Bona fide Service Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Indiana via Federally-mandated, non-recourse "Clawback" payments for Defendants' drug costs in the Medicare Part D program.

860. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Iowa. The State of Iowa has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT FIFTEEN

Louisiana Medical Assistance Programs Integrity Law

La. Rev. Stat.§ 46:438.3(C)

(Against All Defendants)

861. Relator repeats and realleges each and every allegation contained in the paragraphs

above as though fully set forth herein.

862. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the "Bona fide Service Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Louisiana via Federally-mandated, non-recourse "Clawback" payments for Defendants' drug costs in the Medicare Part D program.

863. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Louisiana, within the meaning of La. Rev. Stat. § 46:438.3(C). The State of Louisiana has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT SIXTEEN

Massachusetts False Claims Law

Mass. Gen. Laws ch. 12 §5B(8)

(Against All Defendants)

864. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

865. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the "Bona fide Service Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the Commonwealth of Massachusetts

via Federally-mandated, non-recourse "Clawback" payments for Defendants' drug costs in the Medicare Part D program.

866. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Commonwealth of Massachusetts, within the meaning of Mass. Gen. Laws ch. 12 §5B(8). The Commonwealth of Massachusetts has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT SEVENTEEN

Michigan Medicaid False Claims Act

§400.607(3)

(Against All Defendants)

867. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

868. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the "Bona fide Service Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Michigan via Federally-mandated, non-recourse "Clawback" payments for Defendants' drug costs in the Medicare Part D program.

869. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Michigan, within the meaning of §400.607(3). The State of Michigan has thereby suffered actual damages and is entitled to recover treble damages

and a civil penalty for each false claim.

COUNT EIGHTEEN

Minnesota False Claims Act

Minn. Stat. §§ 15C.01 through 15C.16

(Against All Defendants)

870. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

871. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the "Bona fide Service Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Minnesota via Federally-mandated, non-recourse "Clawback" payments for Defendants' drug costs in the Medicare Part D program.

872. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Minnesota. The State of Minnesota has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT NINETEEN

Montana False Claims Act

Mont. Code Ann. 17-8-403(1)(g)

(Against All Defendants)

873. Relator repeats and realleges each and every allegation contained in the paragraphs

above as though fully set forth herein.

874. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the "Bona fide Service Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Montana via Federally-mandated, non-recourse "Clawback" payments for Defendants' drug costs in the Medicare Part D program.

875. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Montana, within the meaning of Mont. Code Ann. 17-8-403(1)(g). The State of Montana has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY

Nevada Submission of False Claims to State or Local Government Act

Nev. Rev. Stat. Ann. §357.040(1)(g)

(Against All Defendants)

876. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

877. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the "Bona fide Service Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program.

Intentional failure to do so led to fraudulent overpayment by the State of Nevada via Federally-mandated, non-recourse "Clawback" payments for Defendants' drug costs in the Medicare Part D program.

878. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Nevada, within the meaning of Nev. Rev. Stat. Ann. §357.040(l)(g). The State of Nevada has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-ONE

New Jersey False Claims Act

N.J. Stat. §2A:32C-3(g)

(Against All Defendants)

879. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

880. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the "Bona fide Service Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of New Jersey via Federally-mandated, non-recourse "Clawback" payments for Defendants' drug costs in the Medicare Part D program.

881. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of New Jersey, within the meaning of N.J. Stat.

§2A:32C-3(g). The State of New Jersey has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-TWO

New Mexico Medicaid False Claims Act

N.M. Stat. Ann.§ 27-14-3(a)(7)

(Against All Defendants)

882. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

883. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the "Bona fide Service Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of New Mexico via Federally-mandated, non-recourse "Clawback" payments for Defendants' drug costs in the Medicare Part D program.

884. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of New Mexico, within the meaning of N.M. Stat. Ann. § 27-14-3(a)(7). The State of New Mexico has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-THREE

New York False Claims Act

NY CLS St. Fin. §189(g)

(Against All Defendants)

885. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

886. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the "Bona fide Service Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of New York via Federally-mandated, non-recourse "Clawback" payments for Defendants' drug costs in the Medicare Part D program.

887. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of New York, within the meaning of NY CLS St. Fin. §189(g). The State of New York has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-FOUR

North Carolina False Claims Act

2009-554 N.C. Sess. Laws §1-607(a)(7)

(Against All Defendants)

888. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

889. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the "Bona fide Service Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of North Carolina via Federally-mandated, non-recourse "Clawback" payments for Defendants' drug costs in the Medicare Part D program.

890. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of North Carolina, within the meaning of 2009-554 N.C. Sess. Laws §1-607(a)(7). The State of North Carolina has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-FIVE

Oklahoma Medicaid False Claims Act

Okla. Stat. tit. 63, §5053.1B (7)

(Against All Defendants)

891. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

892. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the "Bona fide Service Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Oklahoma via Federally-mandated, non-recourse "Clawback" payments for Defendants' drug costs in the Medicare Part D

program.

893. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Oklahoma, within the meaning of Okla. Stat. tit. 63, §5053.1B (7). The State of Oklahoma has thereby suffered actual damages and is entitled to recover treble Oklahoma damages and a civil penalty for each false claim.

COUNT TWENTY-SIX

Rhode Island State False Claims Act

R.I. Gen. Laws §9-1.1-3(7)

(Against All Defendants)

894. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

895. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the "Bona fide Service Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Rhode Island via Federally-mandated, non-recourse "Clawback" payments for Defendants' drug costs in the Medicare Part D program.

896. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Rhode Island, within the meaning of R.I. Gen. Laws §9-1.1-3(7). The State of Rhode Island has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-SEVEN

Tennessee False Claims Act and
Medicaid False Claims Act
Tenn. Code Ann. §§ 4-18-103(a)(7) and 71-5-181(a)(l)(D)
(Against All Defendants)

897. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

898. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the "Bona fide Service Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Tennessee via Federally-mandated, non-recourse "Clawback" payments for Defendants' drug costs in the Medicare Part D program.

899. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Tennessee, within the meaning of Tenn. Code Ann. §§ 4-18-103(a)(7) and 71-5-18l(a)(l)(D). The State of Tennessee has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-EIGHT

Texas Medicaid Fraud Prevention Act
Tex. Hum. Res. Code Ann. §36.002(12)
(Against All Defendants)

900. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

901. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the "Bona fide Service Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Texas via Federally-mandated, non-recourse "Clawback" payments for Defendants' drug costs in the Medicare Part D program.

902. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Texas, within the meaning of Tex. Hum. Res. Code Ann. §36.002(12). The State of Texas has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-NINE

Virginia Fraud Against Taxpayers Act

Va. Code Ann. §8.01-216.3(a)(7)

(Against All Defendants)

903. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

904. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the "Bona fide Service Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the Commonwealth of Virginia via Federally-mandated, non-recourse "Clawback" payments for Defendants' drug costs in the

Medicare Part D program.

905. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Commonwealth of Virginia, within the meaning of Va. Code Ann. §8.01-216.3(a)(7). The Commonwealth of Virginia has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT THIRTY

Washington Medicaid Fraud False Claims Act

Wash. Sess. Laws, Laws of 2012

Ch. 241 §§ 201 through 214

(Against All Defendants)

906. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

907. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the "Bona fide Service Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Washington via Federally-mandated, non-recourse "Clawback" payments for Defendants' drug costs in the Medicare Part D program.

908. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Washington. The State of Washington has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false

claim.

COUNT THIRTY-ONE

Wisconsin False Claims For Medical Assistance Act

Wis. Stat. §20.931(2)(g)

(Against All Defendants)

909. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

910. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the "Bona fide Service Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Wisconsin via Federally-mandated, non-recourse "Clawback" payments for Defendants' drug costs in the Medicare Part D program.

911. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Wisconsin, within the meaning of Wis. Stat. §20.931(2)(g). The State of Wisconsin has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT THIRTY-TWO

District of Columbia False Claims Act D.C.

Code Ann. §2-308.14(a)(7)

(Against All Defendants)

912. Relator repeats and realleges each and every allegation contained in the paragraphs

above as though fully set forth herein.

913. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the "Bona fide Service Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the District of Columbia via Federally-mandated, non-recourse "Clawback" payments for Defendants' drug costs in the Medicare Part D program.

914. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the District of Columbia, within the meaning of D.C. Code Ann. §2-308.14(a)(7). The District of Columbia has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT THIRTY-THREE

Unjust Enrichment

915. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

916. By virtue of their conduct, Defendants have been unjustly enriched at the expense of the United States. By obtaining money as a result of their violations of federal law, Defendants were unjustly enriched, and are liable to account and pay such amounts to be determined at trial.

917. By this claim, Relator demands a full accounting of all BFSFs (and interest thereon) incurred and/or paid by the Manufacturer Defendants to the PBM Defendants for services and disgorgement of all profits earned and/or imposition of a constructive trust in favor of the United

States.

COUNT THIRTY-FOUR

Common Law Fraud

918. Plaintiff repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

919. Manufacturer Defendants made or caused to be made material and false representations concerning the calculation, for which they are responsible, of the BFSFs that were paid to the PBM Defendants for services that CMS requires be provided at FMV, which representations were made by Service Vendors for Services that CMS requires be provided at FMV, with knowledge of their falsity or with reckless disregard for the truth. The PBM Defendants then knowingly submitted false claims for payment to the United States to act upon those misrepresentations to the United States' detriment. The United States acted in justifiable reliance upon both the Manufacturer Defendants and the PBM Defendants misrepresentations by making payments on the false claims.

920. Had the Manufacturer Defendants and the PBM Defendants made truthful statements, the United States would not have made payments for excessive prices for the Defendants' drugs in Medicare Part D.

921. As a direct and proximate cause of Defendants' conduct, the United States has been damaged in an amount to be determined at trial.

PRAYERS FOR RELIEF

922. WHEREFORE, the Relator acting on behalf of and in the name of the United States of America, and on his own behalf, demands and prays that judgment be entered as follows:

A. That Defendants cease and desist from violating 31 U.S.C. §3729 *et seq.,* and the Anti-Kickback Statute as set forth above;

B. That this Court enter judgment in favor of the United States against the Defendants jointly and severally in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not Eleven Thousand Dollars ($11,000) for each false claim;

C. In favor of the United States against the Defendants for disgorgement of the profits earned by Defendants as a result of their illegal schemes;

D. In favor of the Relator for the maximum amount allowed as a Relator's share pursuant to 31 U.S.C. § 3730(d) and in favor of the Relator against Defendants for reasonable expenses, attorneys' fees and costs incurred by the Relator;

E. In favor of the Relator and the United States and against the Defendants for all costs of this action;

F. In favor of the Relator and the United States and against the Defendants for such other and further relief as this Court deems to be just and equitable.

G. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of California has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Cal. Govt. Code §1651(a);

H. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Colorado has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Colo. Rev. Stat. §§ 25.5-4-303.5 through 25.5-4-310;

I. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Connecticut has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Conn. Gen. Stat. § 17b-301b;

J. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Delaware has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of 6 Del. C. §1201(a);

K. That this Court enter judgment against Defendants in an amount equal to

three times the amount of damages the State of Florida has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of Fla. Stat. Ann. §68.082(2);

L. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Georgia has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of Ga. Code Am1. §49-4-168.1.

M. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Hawaii has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Haw. Rev. Stat. §661-2l(a);

N. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Illinois has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of 740 Ill. Comp. Stat. §175/3(a);

O. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Indiana has sustained because of Defendants' actions, plus a civil penalty of at least $5,000 for each violation of IC 5-11-55;

P. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Iowa has sustained because of Defendants' actions, plus a civil penalty of at least $10,000 for each violation of Iowa Code §§ 685.1 through 685.7;

R. That at this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Louisiana has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of La. Rev. Stat. §437 et. seq.;

S. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the Commonwealth of Massachusetts has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Mass. Gen. L. Ch. 12 §5B;

T. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Michigan has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of MI Public Act 337;

U. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Minnesota has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Minn. Stat. §§ 15C.01 through 15C.16;

V. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Montana has sustained because of Defendants ' actions, plus a civil penalty of $10,000 for each violation of Mont. Stat. Ann. 17-8-401;

W. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Nevada has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Nev. Rev. Stat. Ann. §357.040(1);

X. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Jersey has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of N.J. Stat. §2A:32C-3;

Y. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Mexico has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of N.M. Stat. Ann. §27-2F-4;

Z. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New York has sustained because of Defendants' actions, plus a civil penalty of $12,000 for each violation of NY CLS St. Fin. §189;

AA. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of North Carolina has sustained because of Defendants' actions, plus a civil penalty or $11,000 for each violation of 2009-554 N.C. Sess. Laws §1- 607(a);

BB. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Oklahoma has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Okla. Stat. tit. 63, §5053.1B;

CC. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Rhode Island has sustained because of Defendants'

actions, plus a civil penalty of $10,000 for each violation of R.I. Gen. Laws §9-1.1-3;

DD. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Tennessee has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Tenn. Code Ann. §§4-18-103(a) and 71-5-182(a)(l);

EE. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Texas has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Tex. Hum. Res. Code Ann. §36.002;

FF. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the Commonwealth of Virginia has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of Va. Code Ann. §8.01-216.3(a);

GG. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Wisconsin has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Wis. Stat. §20.931(2);

HH. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Washington has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Wash. Sess. Laws, Laws of 2012, Ch. 241 §§ 201 through 214;

II. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the District of Columbia has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of D.C. Code Ann. §2-308.14(a);

JJ. That Relator be awarded the maximum amount allowed pursuant to§3730(d) of the False Claims Act, and the equivalent provisions of the state statutes set forth above;

KK. That Relator be awarded all costs of this action, including attorneys' fees and expenses; and

LL. That Relator recovers such other relief as the Court deems just and proper.

JURY DEMAND

923. Plaintiff/Relator demands a trial by jury on all counts.

Dated: August 2, 2018

Respectfully Submitted,

RELATOR John R. Borzilleri, M.D.

_____/s_____

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